SUBCHAPTER V. PHARMACY BENEFITS
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INTRODUCTION. The Texas Department of Insurance proposes amendments to 28 TAC Chapter 21, Subchapter V, relating to Pharmacy Benefits. Specifically, TDI proposes amending §§21.3001 - 21.3004, 21.3010, 21.3011, 21.3020, 21.3022, and 21.3023; repealing §21.3005 and §21.3021; and adding new §§21.3030 - 21.3034.

The proposed amendments to §§21.3001 - 21.3004, 21.3010, 21.3011, 21.3020, 21.3022, and 21.3023 are necessary to make nonsubstantive changes to the rule text for consistency with current TDI rule-drafting style; correct typographical, grammatical, and punctuation errors; simplify and clarify certain provisions; update Insurance Code citations; and conform TDI rules to current law.

The proposed amendment to §21.3002(7) is necessary to conform to Insurance Code §1369.151, which states the subchapter is applicable to state employees, Medicaid, and Child Health Insurance Program (CHIP) plans. The proposed amendment to §21.3003 is necessary to conform to Insurance Code §1369.153, which designates what content must be located on the front and back of an identification card. The proposed amendment to §21.3020(7) is necessary to conform to Insurance Code §1369.052 and §1369.053, which state that the subchapter is applicable to individual, small group, and large group health benefit plans, but is not applicable to CHIP and Medicaid Managed Care Organizations, respectively. The amendment to §21.3022 is necessary to conform to Insurance Code §1369.0541,

which specifies conditions under which modifications of drug coverage may occur and adds notice requirements.

The proposed repeal of §21.3005 is necessary because it applies to identification cards that were in effect on September 1, 1999, and is no longer applicable.

The proposed repeal of §21.3021 is intended to streamline the rules implementing Insurance Code Subchapter B. The requirements contained in §21.3021 are proposed to be included in §21.3030(a) in implementing Insurance Code §1369.054.

Proposed new §§21.3030 - 21.3034 are necessary to implement the portions of HB 1624, 84th Legislature, Regular Session (2015) (HB 1624) that added Insurance Code §§1369.0542 - 1369.0544, which require health benefit plan issuers to post on their website formulary information for each health benefit plan they issue.

EXPLANATION. HB 1624 relates to the transparency of certain information related to health benefit plan coverage. During the legislative session, interested parties asserted that health benefit plan issuers do not post complete or easily accessible prescription drug formularies online. The parties noted that there is often no information available to health insurance shoppers about cost-sharing for prescription drugs under the plans until after they purchase a plan.

HB 1624 requires a health benefit plan issuer to display formulary information on a public website maintained by the issuer as required by the commissioner of insurance by rule. The bill requires a direct electronic link to the formulary information to be displayed in a conspicuous manner in the electronic summary of benefits and coverage portion of each plan issued by a health benefit plan issuer on the issuer's website, and it requires the information to be publicly accessible to enrollees, prospective enrollees, and others without necessity of providing a password, user name, or personally identifiable information. The bill also requires a health benefit plan issuer to make plan-specific

formulary information available, including disclosures relating to the cost-sharing amount for each drug, prior authorization requirements, a description of how the drug will be included or excluded from the deductible, and an explanation of coverage of each formulary drug.

HB 1624 requires the commissioner to develop and adopt by rule requirements to promote consistency and clarity in the disclosure of formularies to facilitate comparison shopping among health benefit plans. Proposed new §§21.3030 - 21.3034 implement this requirement. For example, §21.3033 requires a health benefit plan issuer to create a "Summary of Formulary Benefits" designed to help consumers understand the prescription drug benefits offered under the specific plan they are reviewing so they can compare the benefits to those offered by other plans. The information is intended to help consumers compare both the value and scope of the formulary benefits.

TDI posted an informal draft of the rule text on its website on October 2, 2015, and invited public comment. TDI hosted a stakeholder meeting on October 20, 2015, and invited further public comment. TDI accepted and considered all comments received, revised the draft, and makes this proposal.

HB 1624 added Insurance Code §§1369.0542 - 1369.0544, relating to formulary disclosures, and Insurance Code §§1451.501 - 1451.505, relating to health care provider directories. This proposal addresses only the Insurance Code sections relating to formulary disclosures, as new or amended sections are not necessary to implement the Insurance Code sections relating to health care provider directories.

Proposed Amendments. Amendments to Subchapter V divide the subchapter into four new divisions for ease of reference and organizational purposes. New Division 1, titled "General Provisions," encompasses existing §21.3001 and relates to applicability and severability. New Division 2, titled "Identification Cards," encompasses existing §§21.3002 - 21.3004 and relates to pharmacy cards and

standard identification cards. Division 2 will not include §21.3005, as that section is proposed for repeal. New Division 3, titled "Off-Label Drugs," encompasses existing §§21.3010 - 21.3011 and relates to coverage of off-label drugs. New Division 4, titled "Prescription Drug Formulary Coverage and Disclosure Requirements," encompasses existing §§21.3020 - 21.3023 related to continuation of benefits and adverse determination of nonformulary prescription drugs, and newly proposed §§21.3030 - 21.3034 related to required drug formulary disclosures. Provisions contained in repealed §21.3021 are incorporated in §21.3030(a).

Proposed amendments throughout Subchapter V remove the word "group" where it precedes "health benefit plan" to conform with Insurance Code §1369.151. In addition to the substantive amendments and additions, the proposed amendments also contain conforming changes for clarity and agency style, and amendments update Insurance Code citations.

The following explanation provides an overview and description of additional reasoned justification for the proposed amendments to the rules.

§21.3001. Applicability and Severability. A proposed amendment to §21.3001 deletes the word "scope" from the title of the section and replaces it with "applicability." Proposed amendments to §21.3001(a)(1) - (3) add language to clarify which sections in Subchapter V apply to which subchapters of Insurance Code Chapter 1369 and delete text referencing Insurance Code articles that have been recodified.

§21.3002. Definitions; Pharmacy Identification Cards. The proposed amendment to §21.3002(1) deletes and replaces current text with new text that defines "administrator" as it is defined in Insurance Code §4151.001(1).

The proposed amendment to §21.3002(7) replaces current text with new text that defines "health benefit plan" as it is described in Insurance Code §1369.151, and includes a health benefit plan

providing coverage for pharmacy benefits. The amendment also adds the phrase "exempt from state regulation under" to part of the definition, so that part of the definition now reads, "This definition includes the term, 'plan,' as defined in Insurance Code §4151.001(4), but does not include a self-funded employee welfare benefit plan exempt from state regulation under ERISA, 29 U.S.C. §1002(1)(A)."

The proposed amendment to §21.3002(9) replaces current text with new text that defines "issuer" as those entities described in Insurance Code §1369.151, but not those excluded by Insurance Code §1369.152.

The proposed amendment to §21.3002(10) adds new text "exempt from state regulation under" to clarify the definition of "pharmacy benefit manager." The definition now reads, "As defined in Insurance Code §4151.151, but does not include a pharmacy benefit manager for a self-funded employee welfare benefit plan exempt from state regulation under ERISA, 29 U.S.C. §1002(1)(A)."

§21.3003. Standard Identification Cards. The proposed amendment to §21.3003(b) adds the requirement that the information listed in §21.3003(b)(1) - (7) be included on the front of each identification card. The proposed amendment to §21.3003(b)(2) incorporates language from current §21.3003(b)(3) and provides an option to include either the name or logo of the issuer, the administrator, or the pharmacy benefit manager on the front of the card.

Current §21.3003(b)(4) is redesignated §21.3003(b)(3) and current §21.3003(b)(5) is redesignated §21.3003(b)(4). The proposed amendment to current §21.3003(b)(6) moves the text to proposed new §21.3003(c) and redesignates current §21.3003(b)(7) as §21.3003(b)(5), and current §21.3003(b)(8) as §21.3003(b)(6). The proposed amendments to new §21.3003(7) adds the requirement that for a plan issued under Insurance Code Chapters 843 or 1301, the letters "TDI" or "DOI" be prominently displayed on the front of each identification card.

Proposed new §21.3003(c) requires the issuer of a health benefit plan to include the information described in current §21.3003(b)(6) on the identification card of each enrollee, but does not specify which side of the card. Current §21.3003(c) is redesignated §21.3003(d).

§21.3004. Issuance of Standard Identification Cards. Proposed amendments to §21.3004(c) - (d) remove references to §21.3005, as this proposal repeals §21.3005 in its entirety.

§21.3005. Previously Issued Identification Cards. The proposal repeals §21.3005, as both subsections relate to updating information on enrollee identification cards in effect on September 1, 1999, and therefore, are no longer relevant.

§21.3010. Definitions; Coverage of Off-Label Drugs. Proposed amendments to §21.3010 make changes for clarity and agency style and update Insurance Code citations.

§21.3011. Minimum Standards of Coverage for Off-Label Drug Use. Proposed amendments to §21.3011 make changes for clarity and agency style and update Insurance Code citations.

§21.3020. Definitions; Prescription Drug Formulary. Proposed amendments to §21.3020 make changes for clarity and agency style, update Insurance Code citations, and remove the word "group" preceding "health benefit plan" to comply with Insurance Code §1369.052. Proposed revisions to this section also add definitions for terms used in proposed new §§21.3030 - 21.3033.

A proposed amendment to §21.3020(1) deletes the current definition for the term "adverse determination" and replaces it with a reference to the definition for the term as defined in Insurance Code §4201.002.

Proposed new §21.3020(2) adds the term "allowed amount" and defines it as "the amount the health benefit plan issuer allows as reimbursement for a health care service, supply, or prescription

drug, including reimbursement amounts for which a patient is responsible due to deductibles, copayments, or coinsurance." Current §21.3020(2) is redesignated §21.3020(4).

Proposed new §21.3020(3) adds the term "commonly prescribed drug list" and defines it as "a list of the 150 most frequently prescribed drugs published annually by the New York State Board of Pharmacy, available at https://apps.health.ny.gov/pdpw/DrugInfo/DrugInfo.action." Current §21.3020(3) is redesignated §21.3020(5).

A proposed amendment to current §21.3020(4) redesignates it §21.3020(6) and amends the definition of "delegated entity" to clarify that third-party administrators are those defined in Insurance Code §4151.001(1) and pharmacy benefits are those defined in Insurance Code §4151.151.

A proposed amendment to current §21.3020(5) redesignates it §21.3020(9) and amends the defined term to include the words "or formulary."

A proposed amendment to current §21.3020(6) redesignates it §21.3020(10).

Proposed new §21.3020(7) adds the term "direct electronic link" and defines it as "a hyperlink that, when clicked, delivers a user directly to the applicable website destination." Proposed amendments to current §21.3020(7) redesignate it §21.3020(11), remove the word "group" from the defined term, and define it as an insurance policy or evidence of coverage as described in Insurance Code §1369.052, but not those described in Insurance Code §1369.053, that provides coverage for a discrete package of benefits, paired with specific cost-sharing parameters.

Proposed new §21.3020(8) adds the term "drug" and defines it by referencing the definition for the term in the Texas Pharmacy Act, Occupations Code §551.003. A proposed amendment to current §21.3020(8) redesignates it §21.3020(12).

Proposed amendments to current §21.3020(9) - (13) redesignate them §21.3020(15) - (18).

Proposed new §21.3020(14) adds the term "off-label drug use" and defines it as "the use of a drug that is approved by the Food and Drug Administration for the treatment of one medical condition, but is used to treat another medical condition or at different dosage forms, dosage regimens, populations, or other parameters not mentioned in the approved labeling."

Proposed new §21.3020(19) adds the term "summary health plan document" and defines it as "a document summarizing the coverage provided under a health benefit plan, including a summary of benefits and coverage, as required under 42 U.S. Code §300gg-15 and 45 CFR §147.200; and a disclosure of terms and conditions of a policy, as required under §3.3705(b) of this title (relating to Nature of Communications with Insureds; Readability, Mandatory Disclosure Requirements, and Plan Designations), or an evidence of coverage, as required under §11.1600(b) of this title (relating to Information to Prospective and Current Contract Holders and Enrollees)."

§21.3021. Required Disclosure of Drug Formulary. The proposal repeals §21.3021 in order to group all the formulary disclosure requirements in §§21.3030 - 21.3033. The requirements under §21.3021 are included under §21.3030(a) and Insurance Code §1369.054.

§21.3022. Continuation of Benefits. Proposed amendments to §21.3022 remove the word "group" preceding "health benefit plan" to comply with Insurance Code §1369.052.

The proposed amendments also add new text to specify conditions under which health benefit plans may make modifications to drug coverage under Insurance Code §1369.0541. Specifically, the proposed amendment to §21.3022(a) clarifies that modifications to drug coverage are not permitted until the plan's renewal date. The proposed amendment to §21.3022(b) replaces existing text with new text describing the conditions under which a health benefit plan issuer may make modifications to drug coverage. The proposed amendment to §21.3022(c) replaces existing text with new text describing some modifications of drug coverage for the purposes of the section.

§21.3023. Nonformulary Prescription Drugs; Adverse Determination. Proposed amendments to §21.3023 correct typographical, grammatical, and punctuation errors; make changes to conform rule text to current TDI drafting style; update Insurance Code citations; and remove the word "group" preceding "health benefit plan" to comply with Insurance Code §1369.052.

§21.3030. Availability of Formulary Information. Proposed new §21.3030(a) incorporates provisions from repealed §21.3021 and requires an issuer of a health benefit plan or its delegated entity to include plain language disclosures related to formularies in the coverage documentation provided to enrollees, which is consistent with Insurance Code §1369.054. Proposed new §21.3030(b) requires an issuer of a health benefit plan to make a paper copy of the formulary information, which is required under proposed new §21.3032 and §21.3033, available to a current or prospective enrollee on request. Proposed new §21.3030(c) permits a health benefit plan issuer to exclude the plan-level cost-sharing information on the paper copy as long as the enrollee can obtain the information by calling a toll-free number. Proposed new §21.3030(d) requires the paper copy to use at least 10-point font.

§21.3031. Formulary Information on Issuer's Website. Proposed new §21.3031 describes how the issuer of a health benefit plan displays the formulary information required under new proposed §21.3032 and §21.3033.

Proposed new §21.3031(a) requires a health benefit plan issuer to display the formulary information on a website that is publicly accessible without requiring the use of paid software, a password, user name, or personally identifiable information. Proposed new §21.3031(a)(1) - (2) state that formulary information must be electronically searchable by drug name and use at least 10-point font.

Proposed new §21.3031(b) requires that each health plan document include a direct link to the website containing the formulary information and describes the direct-link requirements.

Proposed new §21.3031(c) permits an issuer of a health benefit plan to develop a web-based tool to display plan-specific cost-sharing information required under §21.3032(c). Proposed new §21.3032(c)(1) - (4) describe the required elements that the web-based tool must contain. Section 21.3031(c)(1) requires the web-based tool to be publicly accessible to enrollees, prospective enrollees, and others without the use of a password or user name. Section 21.3031(c)(2) requires the tool to allow consumers to electronically search formulary information by the name under which the health benefit plan is marketed. Section 21.3031(c)(3) requires the tool to contain plan-specific cost-sharing information for each drug. Section 21.3031(c)(3)(A) - (C) describe the plan-specific cost-sharing information the health benefit plan issuer must include. Section 21.3031(c)(4) requires that the tool include a direct electronic link to a chart displaying each formulary that applies to each health benefit plan issued by the health benefit plan issuer and include 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. Proposed new §21.3032(a) requires the information provided under the section to include each prescription drug dispensed in a pharmacy or administered by a physician, and must differentiate between drugs covered under the plan's pharmacy benefits and medical benefits. Proposed new §21.3032(b)(1)- (4) describe the coverage information that must be included for each drug.

Proposed new §21.3032(c) requires the formulary information to include plan-specific cost-sharing information for each drug. Proposed new §21.3032(c)(1) requires the formulary information to indicate whether the drug is subject to a pharmacy or medical deductible and the amount of the deductible. Proposed new §21.3032(c)(2) requires the formulary information to include the cost-sharing amount for each drug under the pharmacy or medical benefit in a retail, mail order, or physician-

administered setting, if applicable, after the enrollee has met any deductible requirement. Proposed new §21.3032(c)(2)(A) - (B) describe the cost-sharing information that must be included.

Proposed new §21.3032(d) requires the cost-sharing amounts to reflect the cost to the consumer for a month-long supply of the prescribed drug, unless otherwise noted, and it describes the requirements for calculating the cost-sharing amount for the drug.

Proposed new §21.3032(e) requires a legend on each page of the formulary information, and it describes required elements of the legend.

§21.3033. Facilitating Comparison Shopping. Proposed new §21.3033(a) requires that the formulary information must include a summary titled "Summary of Formulary Benefits." The summary is designed to help current and prospective enrollees understand the prescription drug benefits offered under the plan and to compare the benefits in one plan to those offered by other plans. Proposed new §21.3033(a)(1) - (5) describe the title of each section of the summary, the elements the summary must include, and the order in which to include them.

Proposed new §21.3033(a)(1) requires a section in the summary titled "How to Find Information on the Cost of Prescription Drugs," which explains how a consumer can determine cost-sharing from the plan's summary health plan document, formulary information, and web-based tool, if applicable.

Proposed new §21.3033(a)(2) requires a section in the summary titled "Formulary by Health Benefit Plan," which includes a chart displaying each formulary that applies to each health benefit plan issued by the issuer and 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 health benefit plan is issued.

Proposed new §21.3033(a)(3) requires a section in the summary titled "Drugs by Cost-Sharing Tier," which includes information on drugs by cost-sharing tier, if applicable. Proposed new §21.3033(a)(3)(A) - (B) describe the cost-sharing tier information an issuer must include.

Proposed new §21.3033(a)(4) requires a section titled "Coverage for Commonly Prescribed Drugs," which includes information on coverage for commonly prescribed drugs. Proposed new §21.3033(a)(4)(A)(i) - (ii) describe the information to include if drugs from the commonly prescribed drug list are included in the formulary. Proposed new §21.3033(a)(4)(B) describes the information to include if drugs from the commonly prescribed drug list are not included in the formulary.

Proposed new §21.3033(a)(5) requires a section in the summary titled "How Prescription Drugs are Covered under the Plan," which includes information on how prescription drugs are covered under the plan. Proposed new §21.3033(a)(5)(A) - (F) describe the information an issuer must include in the summary.

Proposed new §21.3033(a)(5)(A) requires a section in the summary titled "Formulary Composition," which explains the method the health benefit plan issuer uses to determine the prescription drugs to include or exclude from the formulary, whether the formulary is open or closed, and a statement on how often the issuer reviews the formulary.

Proposed new §21.3033(a)(5)(B) requires a section in the summary titled "Right to Appeal," which explains an enrollee's right to appeal a denial of a medically necessary drug that is not covered under the formulary.

Proposed new §21.3033(a)(5)(C) requires a section in the summary titled "Continuation of Coverage," which explains the consumer's right to continued coverage consistent with proposed amended §21.3022 and Insurance Code §1369.055 and §1369.0541.

Proposed new §21.3033(a)(5)(D) requires a section in the summary titled "Off-Label Drug Use," which explains coverage for off-label drug use.

Proposed new §21.3033(a)(5)(E) requires a section in the summary titled "Cost-Sharing," which explains how cost-sharing is determined under the plan, including: information on deductibles; formulary tiers or cost-sharing levels if the formulary is multitier; the difference between preferred and nonpreferred drugs, if applicable; differences in coverage for in-network and out-of-network pharmacies; and the difference in coverage between retail pharmacy and mail-order pharmacy, if applicable.

Proposed new §21.3033(a)(5)(F) requires a section in the summary titled "Medical Management Requirements," which explains each type of medical management requirement used by the health benefit plan, including prior authorization, step therapy, or other protocol requirements that limit access to prescription drugs, as applicable.

Proposed new §21.3033(b) requires the summary information under proposed new subsection (a) to be located on the first page of the formulary document under the title "Summary of Formulary Benefits."

§21.3034. Effective Date. Proposed new §21.3034 states the effective dates of proposed new §§21.3030 - 21.3033. Proposed new §21.3034(a) provides the effective date for plans being marketed in the individual market, and proposed new §21.3034(b) provides the effective date for plans being marketed in the group market.

FISCAL NOTE. Rachel Bowden, program specialist, Regulatory Initiatives Office, 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 also be 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.

Anticipated Public Benefits.

The anticipated public benefits are the implementation of rules necessary to comply with HB 1624 and increased transparency of formulary information for consumers so they can easily compare and shop among plans. Health benefit plan issuers will publish formulary information that is plan specific, discloses cost-sharing information, and contains a summary of formulary benefits.

Anticipated Costs.

Proposed New §21.3030. Availability of Formulary Information. There are compliance costs associated with proposed §21.3030. The probable cost components for compliance include the cost of printing, copying, and mailing formularies on request to prospective or current enrollees. TDI estimates the average price of a standard business-size envelope is between $.07 and $.17, and a business catalog-size envelope is between $.31 and $.40. TDI further estimates that the cost of printing or copying is between $.08 and $.12 per page. According to the United States Postal Service, the price to mail a domestic first class letter (one ounce) is $.49. The price of each additional ounce is $.21. It is not feasible for TDI to estimate the total increased printing, copying, and mailing costs attributable to compliance with the proposed section because it is unknown at this time how many prospective or current enrollees

will request a paper copy of the formulary information, or how many formularies prospective or current enrollees will request.

Proposed New §21.3031. Formulary Information on Issuer Website and §21.3032. Formulary Disclosure Requirements. The compliance costs associated with the proposed rules in §21.3031 and §21.3032 are largely statutory, and these sections of the rules will not increase the cost of compliance with Insurance Code §§1369.0542 - 1369.0544 beyond those required by statute. The statutory costs include development of a web page to house the required formulary information, a direct link to the web page from the issuer's health plan documents, and compilation of the required formulary disclosures. Health benefit plan issuers may also incur costs if they choose to develop a web tool to display the cost-sharing amount for each drug.

Proposed New §21.3033. Facilitating Comparison Shopping. There are also compliance costs associated with proposed §21.3033. The probable cost components associated with compliance include compiling the required information to create a "Summary of Formulary Benefits" document, reviewing the summary, and posting the summary online. TDI has identified four categories of labor reasonably necessary to perform the tasks and estimates a total of 40 to 120 hours combined labor time to complete the tasks. The total cost will vary depending on how many variations of the summary are required, how the hours are dispersed across the labor categories, and by the health benefit plan issuer's existing information systems and staffing.

An issuer may calculate the total cost of labor for each category by multiplying the number of estimated hours for each cost component by the median hourly wage for each category of labor. The four categories of labor and their mean hourly wage described in the latest State Occupational Employment and Wage Estimates for Texas published by the United States Department of Labor (May 2014) at http://www.bls.gov/oes/current/oes_tx.htm are as follows: general and operations manager,

$59.16; computer programmer, $38.85; compliance officer, $33.06; and administrative assistant, $25.52.

Health benefit plan issuers may incur additional costs for printing, copying, and mailing the summary to prospective and current enrollees on request. These costs are the same as the costs assessed to comply with §21.3032 (relating to Formulary Disclosure Requirements), discussed above.

Stakeholder Feedback on Costs.

TDI requested cost information by public comment during the posting of the informal draft of the rule text and at the October 20, 2015, stakeholder meeting. TDI received general input that the cost of implementing the statutory requirements proposed in new §§21.3030 - 21.3033 will be costly to implement. TDI is not able to modify the statutory requirements, and the proposed new rules implementing the statutory requirements do not increase the cost of compliance with the statute. In order to mitigate the cost of compliance, TDI proposed a phased-in implementation period in §21.3034.

TDI also received general input regarding the cost of implementing the proposed rule requirements in §21.3030 and §21.3033. Based on this information, TDI proposes §21.3030(c) to permit a paper copy of the formulary information to exclude plan-level cost-sharing information and reduced the number of reporting requirements in §21.3033 to minimize potential costs.

ECONOMIC IMPACT STATEMENT AND REGULATORY FLEXIBILITY ANALYSIS FOR SMALL AND MICRO BUSINESSES.

Economic Impact Statement.

As required by Government Code §2006.002(c), TDI has determined that the proposed amendments will have an adverse economic effect on small or micro businesses that must comply with the rules. The adverse economic impact will result from the cost components associated with printing

and mailing paper copies of the formulary information in §21.3030, and creating and making available a summary of formulary benefits in §21.3033. The cost of compliance with these proposed rules will not vary between large businesses and small or micro businesses, and TDI's cost analysis and resulting estimated costs in the Public Benefit and Cost Note portion of this proposal are equally applicable to large businesses and small or micro businesses.

Regulatory Flexibility Analysis.

Government Code §2006.002(c)(2) requires a state agency, before adopting a rule that may have an adverse economic effect on small businesses, to prepare a regulatory flexibility analysis that includes the agency's consideration of alternative methods of achieving the purpose of the proposed rule. Government Code §2006.002(c)(1) requires that the analysis consider, if consistent with the health, safety, and environmental and economic welfare of the state, using regulatory methods that will accomplish the objectives of applicable rules while minimizing adverse impacts on small businesses.

TDI considered the following three additional regulatory alternatives: (i) not proposing the new rules requirements at §21.3030 or §21.3033; (ii) proposing different requirements for small and micro businesses; and (iii) exempting small and micro businesses. For the following reasons, TDI rejected each of these alternatives as not being sufficiently consistent with the purpose of the statute.

Not proposing the new rules requirements at §21.3030 or §21.3033. The primary objective of the proposal is to provide consumers with complete and easily accessible formulary information consistent with HB 1624. The proposed rules promote consistency and clarity in the disclosure of formularies to facilitate consumer comparison shopping among health benefit plans and make the disclosures available to all consumers regardless of Internet access. Not proposing rules would conflict with the intent of the statute.

Proposing Different Requirements for Small and Micro Businesses. As previously noted, a purpose of the proposal is to provide consistent formulary disclosures to facilitate comparison shopping for health insurance. The formulary disclosures would not be consistent if small or micro business health benefit plan issuers reported different or less information than large businesses. Proposing different requirements for small or micro businesses would frustrate the intent of the statute.

Exempting small and micro businesses. Finally, TDI has determined that exempting small and micro business health benefit plan issuers from the requirements of the proposed rules would also conflict with the intent of the statute and would not improve the ability of patients to make appropriate and cost-effective health care decisions. For example, consumers already enrolled in a health benefit plan issued by a small or micro business issuer would not be able to compare their current formulary with the formularies offered by other small or micro business issuers of health plans in the market. Similarly, prospective consumers would also not be able to comparison shop.

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.

REQUEST FOR PUBLIC COMMENT. TDI invites comments on the proposed rules. If you wish to comment on this proposal, your comments must be postmarked no later than 5 p.m., Central time, on March 7, 2016. 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 Rachel Bowden, Regulatory

Initiatives 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.

TDI will hold a hearing on the proposed rules from 9:30 a.m. to noon, Central time, on February 24, 2016, in Room 100 of the William P. Hobby Jr. State Office Building, 333 Guadalupe Street, Austin, Texas 78701. TDI will consider all written comments received before the deadline and all written and oral comments on these proposed rules presented at the hearing.

SUBCHAPTER V. PHARMACY BENEFITS

DIVISION 1. GENERAL PROVISIONS

28 TAC §21.3001

STATUTORY AUTHORITY. The amendments to §21.3001 are proposed under Insurance Code §§1369.005, 1369.057, 1369.151, 1369.154, and 36.001. Section 1369.005 provides that the commissioner may adopt rules to implement Insurance Code Chapter 1369, Subchapter A; §1369.057 provides that the commissioner may adopt rules to implement Insurance Code Chapter 1369, Subchapter B; §1369.151 extends the applicability of Insurance Code Chapter 1369, Subchapter D to include state employee, Medicaid, and CHIP plans; §1369.154 provides that the commissioner may adopt rules to implement Insurance Code Chapter 1369, Subchapter D; and §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. The proposed amendments to §§21.3001 affect the following statutes: Insurance Code §§36.001, 1369.005, 1369.057, 1369.151, and 1369.154.

DIVISION 1. GENERAL PROVISIONS

§21.3001. Applicability [~~Scope~~] and Severability.

(a) Applicability [~~Scope~~]. This subchapter implements the provisions of Insurance Code Chapter 1369[~~Articles 21.07-6, Sec. 19A; 21.52J; 21.53L; and 21.53M~~] as follows:

(1) Division 2 of this Subchapter applies to a health benefit plan that is subject to Insurance Code Chapter 1369, Subchapter D [~~Sections 21.3002 - 21.3005 of this subchapter implement the provisions of Insurance Code Articles 21.07-6, Sec. 19A, and 21.53L~~], and relates [~~relate~~] 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 [~~Sections 21.3010 - 21.3011 of this subchapter implement the provisions of Insurance Code Article 21.53M~~], and relates [~~relate~~] 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 [~~Sections 21.3020 - 21.3023 of this subchapter implement the provisions of Insurance Code Article 21.52J~~], and relates [~~relate~~] to the use of a drug formulary by a [~~group~~] health benefit plan.

(b) Severability. If a court of competent jurisdiction holds that any provision of this subchapter is inconsistent with any statute [~~statutes~~] of this state, is unconstitutional, or for any other reason is invalid, the remaining provisions [~~shall~~] 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 [~~shall remain~~] in full effect as to other persons or circumstances.

SUBCHAPTER V. PHARMACY BENEFITS

DIVISION 2. IDENTIFICATION CARDS

28 TAC §§21.3002 - 21.3004

STATUTORY AUTHORITY. The amendments to §§21.3002 - 21.3004 are proposed under Insurance Code §§843.209, 1369.052, 1369.151, 1369.153, 1369.154, 1369.154, §1301.162, and 36.001. Section 843.209 requires that HMO identification cards indicate that the HMO is regulated under the Insurance Code; §1369.052 extends the applicability of Subchapter B to individual, small group, and large group health benefit plans; §1369.151 extends the applicability of Insurance Code Chapter 1369, Subchapter D to include state employee, Medicaid, and CHIP plans; §1369.153 designates identification card content that must be located on the front of the card; §1369.154 provides that the commissioner may adopt rules to implement Chapter 1369, Subchapter D; §1301.162 requires that identification cards issued by insurers regulated by the Insurance Code display the first date on which an individual became insured under the plan or a toll-free number a physician or health care provider may use to obtain that date; and §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. The proposed amendments to §§21.3002 - 21.3004, affect the following statutes: Insurance Code Chapters 843 and 1301; and §§36.001, §1301.162, 1369.052, 1369.151, 1369.153, 1369.154, 1451.001(1) and (4), and 4151.151.

DIVISION 2. IDENTIFICATION CARDS

§21.3002. Definitions; Pharmacy Identification Cards.

The following words and terms, when used in this division, [~~§§21.3002 - 21.3005 of this subchapter~~] [~~shall~~] have the following meanings, unless the context clearly indicates otherwise:

(1) Administrator--As defined in Insurance Code §4151.001(1), for plans subject to Insurance Code Chapter 1369, Subchapter D [~~Article 21.07-6, §1(1), but does not include an administrator for a self-funded employee welfare benefit plan covered by the federal Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. §1002(1)(A)~~].

(2) Drug--As defined in the Texas Pharmacy Act, Occupations Code §551.003.

(3) Drug formulary--A list of drugs for which a health benefit plan provides coverage, approves payment, or encourages or offers incentives for physicians or other health care providers to prescribe.

(4) Effective date--The date that the health benefit plan's current prescription drug benefit levels became effective, or the date the subscriber's coverage first became effective, whichever is later.

(5) Enrollee--A person covered by a health benefit plan.

(6) Enrollee identification card--A printed card issued to enrollees of a health benefit plan that includes all necessary information to allow an enrollee to access all coverage under the health benefit plan.

(7) Health benefit plan--As described in Insurance Code §1369.151 [~~Article 21.53L~~], including a health benefit plan providing coverage for pharmacy benefits only, but not those described in Insurance Code §1369.152. This definition includes the term, "plan," as defined in Insurance Code §4151.001(4) [~~Article 21.07-6, §1(6)~~], but does not include a self-funded employee welfare benefit plan exempt from state regulation under [~~covered by~~] ERISA, 29 U.S.C. §1002(1)(A).

(8) Identification code--Any unique code used [~~utilized~~] by an issuer of a health benefit plan, administrator, or pharmacy benefit manager that identifies and differentiates among [~~amongst~~] enrollees.

(9) Issuer--Those entities described [~~identified~~] in Insurance Code §1369.151, but not those excluded by Insurance Code §1369.152 [~~Article 21.53L, §2(a)(1) - (8)~~].

(10) Pharmacy benefit manager--As defined in Insurance Code §4151.151 [~~Article 21.07-6, §1(9)~~], but does not include a pharmacy benefit manager for a self-funded employee welfare benefit plan exempt from state regulation under [~~covered by~~] ERISA, 29 U.S.C. §1002(1)(A).

(11) Pharmacy benefits--Coverage in a health benefit plan for prescription drugs that are ordinarily and customarily dispensed by a pharmacy or pharmacist licensed under the Texas Pharmacy Act, Occupations Code §551.001, et seq.

(12) Standard identification card--A printed card containing the written information required by §21.3003(b) of this title [~~subchapter~~] (relating to Standard Identification Cards).

(13) Subscriber--The individual who is the contract holder and who is responsible for payment of premiums to the issuer of an individual health benefit plan; or the individual who is the certificate holder and whose employment or membership status, except for family dependency, is the basis for eligibility for enrollment in a [~~group~~] health benefit plan.

§21.3003. Standard Identification Cards.

(a) The issuer of a health benefit plan that provides pharmacy benefits, or a pharmacy benefit manager or administrator issuing standard identification cards to enrollees must [~~shall~~] issue standard identification cards as follows:

(1) For a subscriber who is an enrollee, and who has no enrolled dependents, a single card must [~~shall~~] be issued to the subscriber, with additional cards available on [~~upon~~] request.

(2) For a subscriber who is an enrollee, and who has enrolled dependents, either:

(A) a card must [~~shall~~] be issued to the subscriber and to each of the enrolled dependents, with additional cards available on [~~upon~~] request; or

(B) two cards must [~~shall~~] be issued to the subscriber for use by the subscriber and all enrolled dependents, with additional cards available on [~~upon~~] request.

(3) For coverage under an individual health benefit plan in which the subscriber is not an enrollee, or for coverage under a [~~group~~] health benefit plan that[~~which~~] is continued by an enrollee under[~~pursuant to~~] Insurance Code Chapter 1251, Subchapter E[~~Article 3.51-6, §3B~~], either:

(A) a card must [~~shall~~] be issued to each enrollee, with additional cards available on [~~upon~~] request; or

(B) two cards must [~~shall~~] be issued for use by all enrollees, with additional cards available on [~~upon~~] request.

(b) Each standard identification card issued must [~~shall~~], at all times the card is in effect, include current information on the front of each identification card as follows:

(1) the enrolled subscriber's or enrolled dependents' names and identification codes, as follows:

(A) for [~~For~~] cards issued under [~~pursuant to~~] subsection (a)(1) of this section, the enrolled subscriber's name and identification code;

(B) for [~~For~~] cards issued under [~~pursuant to~~] subsection (a)(2)(A) of this section, the enrolled subscriber's name and identification code on the enrolled subscriber's card, and on each

enrolled dependent's card, the name and identification code of the enrolled dependent to whom the card will be issued;

(C) for [~~For~~] cards issued under [~~pursuant to~~] subsection (a)(2)(B) of this section, the names and identification codes of the enrolled subscriber and the names and identification codes of all the enrolled dependents;

(D) for [~~For~~] cards issued under [~~pursuant to~~] subsection (a)(3)(A) of this section, on each enrolled dependent's card, the name and identification code of the enrolled dependent to whom the card will be issued;

(E) for [~~For~~] cards issued under [~~pursuant to~~] subsection (a)(3)(B) of this section, the names and identification codes of all enrolled dependents;

(2) [~~if applicable,~~] the name or logo of the issuer, or of the administrator or pharmacy benefit manager that is administering the pharmacy benefits, if different from the health benefit plan issuer;

[~~(3) the name or logo of the administrator or pharmacy benefit manager that is administering the pharmacy benefits, if different from the health benefit plan;~~]

(3)[~~(4)~~] as applicable, the group number applicable to the enrollee(s) covered by a group health benefit plan or the policy number or evidence of coverage number applicable to the enrollee(s) covered by an individual health benefit plan;

(4)[~~(5)~~] the effective date of coverage;

[~~(6) a telephone number of an appropriate person for purposes of obtaining information relating to the pharmacy benefits provided under the health benefit plan;~~]

(5)[~~(7)~~] as applicable, the corresponding copayment or coinsurance for generic and brand-name drugs; provided that, if the health benefit plan uses a drug formulary with benefit levels in

addition to generic and brand-name prescription drugs, the card must [~~shall~~] include the corresponding copayments or coinsurance for each tier level of the drug formulary. In addition to disclosure of each benefit level, the card may include a term such as "variable," to reflect benefit designs not fully revealed by the drug formulary tier disclosure; [~~and~~]

(6)[~~(8)~~] as applicable, the International Identification Number, also known as the Banking Identification Number, assigned to the administrator or pharmacy benefit manager by the American National Standards Institute; and[~~.~~]

(7) for a plan issued under Insurance Code Chapters 843 or 1301, the letters "TDI" or "DOI" prominently displayed.

(c) In addition to the information required under subsection (b) of this section, the issuer of a health benefit plan must include on the identification card of each enrollee a telephone number of an appropriate person for purposes of obtaining information relating to the pharmacy benefits provided under the health benefit plan.

(d)[~~(c)~~] Nothing in this section prohibits the issuer of a health benefit plan, or an administrator or pharmacy benefit manager, from issuing a standard identification card containing a magnetic strip or other technological component enabling the electronic transmission of information, provided that the information required by subsections [~~subsection~~] (b) and (c) of this section is printed on the card.

§21.3004. Issuance of Standard Identification Cards.

(a) An issuer of a health benefit plan, or an administrator or pharmacy benefit manager, is not required to issue a standard identification card in addition to an enrollee identification card if:

(1) the enrollee identification card contains the information required by §21.3003(b) and (c) of this title [~~subchapter~~] (relating to Standard Identification Cards); and

(2) the enrollee identification card is issued in accordance with §21.3003(a) of this title [~~subchapter~~] and subsections (c) and (d) of this section.

(b) Under [~~Pursuant to~~] subsection (a) of this section, if a standard identification card is required to be issued, and an administrator or pharmacy benefit manager administers a health benefit plan of an issuer, the administrator or pharmacy benefit manager and the issuer must [~~shall~~] enter into an agreement as to which entity will issue the standard identification card in accordance with this subchapter.

(c) If [~~Subject to §21.3005(a) and (b) of this subchapter (relating to Previously Issued Identification Cards), when~~] an administrator or pharmacy benefit manager for a health benefit plan is designated or required to issue a standard identification card, the administrator or pharmacy benefit manager must [~~shall~~] issue the standard identification card in accordance with this subchapter not later than the 30th calendar day after the date the administrator or pharmacy benefit manager receives notice from the issuer[~~,~~] or [~~from~~] the health benefit plan[~~,~~] that the enrollee is eligible for the pharmacy benefits.

(d) [~~Subject to §21.3005(a) and (b),~~] If [~~if~~] the issuer of a health benefit plan is required to issue a standard identification card, the issuer of the health benefit plan must [~~shall~~] issue the standard identification card in accordance with this subchapter not later than the 30th calendar day after the enrollee is eligible for pharmacy benefits.

SUBCHAPTER V. PHARMACY BENEFITS

DIVISION 3. OFF-LABEL DRUGS

28 TAC §21.3010 and §21.3011

STATUTORY AUTHORITY. The amendments are proposed under Insurance Code §§36.001, 1369.004, and 1369.005. Section 1369.004 describes the drug coverage a health benefit plan that covers drugs is required to provide for treatment of an enrollee for a chronic, disabling, or life-threatening illness; 1369.005 provides that the commissioner may adopt rules to implement Insurance Code Chapter 1369, Subchapter A; and §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. The proposed amendments to §21.3010 and §21.3011 affect the following statutes: Insurance Code §§36.001, 1369.001(1) and (3), 1369.002, 1369.004, and 1369.005.

DIVISION 3. OFF-LABEL DRUGS

§21.3010. Definitions; Coverage of Off-Label Drugs.

The following words and terms, when used in this division [~~§§21.3010 - 21.3011 of this subchapter (relating to off-label drugs) shall~~] have the following meanings, unless the context clearly indicates otherwise:

(1) Chronic illness--A disease, syndrome, or condition of expected long duration, showing little change or slow progression.

(2) Contraindication--As defined in Insurance Code §1369.001(1) [~~Article 21.53M~~].

(3) Disabling illness--A disease, syndrome, or condition determined by an enrollee's health care practitioner to have caused or have the potential to cause:

(A) a physical or mental impairment that substantially limits, or may limit, one or more of the activities of daily living of the enrollee including, but not limited to, eating, bathing,

dressing, grooming, routine hair and skin care, meal preparation, exercising, toileting, and transfer and ambulation;

(B) an impairment substantially limiting an enrollee's cognitive acuity;

(C) an impairment substantially limiting an enrollee's ability to work, home make [~~home-make~~], or engage in leisure or educational activities; or

(D) a condition regarded as an impairment by an enrollee's licensed health care practitioner.

(4) Drug--As defined in the Texas Pharmacy Act, Occupations Code §551.003.

(5) Enrollee--A person covered by a health benefit plan.

(6) Health benefit plan--As described in Insurance Code §1369.002, but not those described in §1369.003 [~~Article 21.53M~~]. This term includes health benefit plans providing coverage for pharmacy benefits only.

(7) Health care practitioner--An advanced practice nurse, doctor of medicine, doctor of dentistry, physician assistant, doctor of osteopathy, doctor of podiatry, or other licensed person with prescriptive authority.

(8) Impairment--Any loss or abnormality of psychological, physiological, or anatomical structure or function.

(9) Indication--As defined in Insurance Code §1369.001(3) [~~Article 21.53M~~].

(10) Issuer--Those entities described [~~identified~~] in Insurance Code §1369.002, but not those excluded by Insurance Code §1369.003 [~~Article 21.53M, §2(a)(1)-(8)~~].

(11) Life-threatening illness--A disease or condition for which the likelihood of death is probable unless the course of the disease or condition is interrupted.

(12) Off-label drug use--The use of a drug that is approved by the Food and Drug Administration for the treatment of one medical condition but is used to treat another medical condition, or at different dosage forms, dosage regimens, populations, or other parameters not mentioned in the approved labeling.

(13) Peer-reviewed medical literature--A published scientific study in a journal or other publication in which original manuscripts are published only after they have been critically reviewed by unbiased independent experts in the same field [~~,~~] for scientific accuracy, validity, and reliability, and have been determined by the International Committee of Medical Journal Editors to have met the Uniform Requirements for Manuscripts submitted to biomedical journals. Peer-reviewed medical literature does not include publications or supplements to publications [~~that are~~] sponsored to a significant extent by a pharmaceutical manufacturing company or an issuer of a health benefit plan.

(14) Standard drug reference compendia--

(A) The American Hospital Formulary Service-Drug Information; or

(B) The United States Pharmacopoeia-Drug Information.

§21.3011. Minimum Standards of Coverage for Off-Label Drug Use.

(a) An issuer of a health benefit plan that provides coverage for drugs must [~~shall~~] provide coverage for any drug prescribed to treat an enrollee for a covered chronic, disabling, or life-threatening illness if the drug:

(1) has been approved by the Food and Drug Administration for at least one indication; and

(2) is recognized for treatment of the indication for which the drug is prescribed in:

(A) a standard drug reference compendium; or

(B) substantially accepted peer-reviewed medical literature.

(b) Coverage of a drug required under subsection (a) of this section:

(1) must [~~shall~~] include services medically necessary to administer the drug, including any supply medically necessary to administer the drug, if the supply is a covered benefit under the health benefit plan;

(2) may be denied based on a finding that the use of the drug is not medically necessary to treat the enrollee's disease, syndrome, or condition, so long as the finding is not based on the fact that the drug is being prescribed for an off-label use;

(3) may not be denied solely on the basis that the drug does not appear on the formulary. If the issuer of a health benefit plan refuses to provide an off-label drug that is not included in a drug formulary, and the enrollee's physician or provider has determined is medically necessary for an off-label use, the refusal constitutes an adverse determination for purposes of Insurance Code §4201.002(1) [~~Article 21.58A, §2~~]. An enrollee may appeal the adverse determination under Insurance Code Chapter 4201, Subchapters H and I [~~§§6 and 6A of Article 21.58A~~];

(4) may be denied for a drug prescribed to treat any disease or condition that is excluded from coverage under the health benefit plan;

(5) may be denied for a drug prescribed for outpatient use if coverage of drugs under that particular health benefit plan is limited to the hospitalization of the enrollee; or

(6) may be denied for a drug that the Food and Drug Administration has determined to be a contraindication for treatment of the current disease or condition.

SUBCHAPTER V. PHARMACY BENEFITS

DIVISION 4. PRESCRIPTION DRUG FORMULARY COVERAGE AND DISCLOSURE REQUIREMENTS

28 TAC §§21.3020, 21.3022, 21.3023, 21.3030 - 21.3034

STATUTORY AUTHORITY. The amendments to §§21.3020, 21.3022, 21.3023 and new sections 21.3030-21.3034 are proposed under Insurance Code §§1369.005, 1369.052, 1369.053, 1369.054, 1369.0541, 1369.0542; 1369.0543, 1369.0544, 1369.055, 1369.056, 1369.057, 1369.151, 1369.154, and 36.001. Section 1369.005 provides that the commissioner may adopt rules to implement Insurance Code Chapter 1369, Subchapter A; §1369.052 extends the applicability of Subchapter B to individual, small group, and large group health benefit plans; §1369.053 provides exceptions to the applicability of Insurance Code Subchapter B, and it exempts CHIP and Medicaid Managed Care Organizations; §1369.054 describes the notice and disclosure of certain information required if an issuer of a health benefit plan covers prescription drugs and uses one or more drug formularies to specify the prescription drugs covered under the plan; §1369.0541 specifies conditions under which modifications of drug coverage may occur and creates notice requirements; §1369.0542 requires a health benefit plan issuer to post formulary information on its website as required by the commissioner by rule; §1369.0543 describes the required formulary disclosures and requires the commissioner to adopt rule requirements to promote consistency and clarity in the disclosure of formularies to facilitate consumers when comparison shopping among health benefit plans; §1369.0544 allows a health benefit plan issuer to make the formulary information available through a toll-free telephone number; §1369.055 describes the continuation of drug coverage requirements an issuer of a health benefit plan must offer if prescription drugs are covered; §1369.056 describes the circumstances under which a refusal of a health benefit plan issuer to provide benefits to an enrollee for a prescription drug is an adverse determination; §1369.057 provides that the commissioner may adopt rules to implement Insurance Code Chapter 1369, Subchapter B; §1369.151 extends the applicability of Insurance Code Chapter 1369, Subchapter D to

include state employee, Medicaid, and CHIP plans; §1369.154 provides that the commissioner may adopt rules to implement Insurance Code Chapter 1369, Subchapter D; and §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. The proposed amendments to §§21.3020, 21.3022, 21.3023 and new sections 21.3030-21.3034 affect the following statutes: Insurance Code §§36.001, 1369.005, 1369.052, 1369.053, 1369.054, 1369.0541, 1369.0542; 1369.0543, 1369.0544, 1369.055, 1369.056, 1369.057, 1369.151, 1369.154, 4201.002, and 4151.001(1) and (4).

DIVISION 4. PRESCRIPTION DRUG FORMULARY COVERAGE AND DISCLOSURE REQUIREMENTS

§21.3020. Definitions; Prescription Drug Formulary.

The following words and terms, when used in this division [~~§§ 21.3020-21.3023 of this subchapter (relating to prescription drug formulary benefits), shall~~] have the following meanings, unless the context clearly indicates otherwise:

(1) Adverse determination--As defined in Insurance Code §4201.002. [~~A determination upon utilization review that the health care services furnished or proposed to be furnished to an enrollee are not medically necessary or not appropriate.~~]

(2) Allowed amount--The amount that the applicable health benefit plan issuer allows as reimbursement for a health care service, supply, or prescription drug, including reimbursement amounts for which a patient is responsible due to deductibles, copayments, or coinsurance.

(3) Commonly prescribed drug list--A list of the 150 most frequently prescribed drugs published annually by the New York State Board of Pharmacy, available at https://apps.health.ny.gov/pdpw/DrugInfo/DrugInfo.action.

(4) [~~(2)~~] Contracted benefit level--The copayment amount or coinsurance percentage established at the beginning of the current plan year and described [~~set forth~~] in the coverage documentation.

(5) [~~(3)~~] Coverage documentation--A policy, certificate of coverage, evidence of coverage, enrollee handbook, or a plan document distributed by an issuer [~~,~~] or its delegated entity [~~,~~] to an enrollee or to the master contract holder, for distribution to enrollees.

(6) [~~(4)~~] Delegated entity--An entity, or an association of [~~which by itself or through one or more~~] entities, including [~~but not limited to~~] third-party administrators, as they are defined in Insurance Code §4151.001(1), and pharmacy benefit managers, as they are defined in Insurance Code §4151.151, that [~~as those terms are defined in Insurance Code Article 21.07-6, which~~] provides reimbursement for covered services or undertakes to arrange for or provide benefits or services to an enrollee under a [~~group~~] health benefit plan, and that [~~which~~] performs on behalf of the issuer of a [~~group~~] health benefit plan, any function regulated by this division [~~§§21.3020 - 21.3023 of this subchapter~~].

(7) Direct electronic link--A hyperlink that, when clicked, delivers a user directly to the applicable website destination.

(8) Drug--As defined in the Texas Pharmacy Act, Occupations Code §551.003.

(9) [~~(5)~~] Drug formulary or formulary--A list of drugs for which a health benefit plan provides coverage, approves payment, or encourages or offers incentives for physicians or other health care providers to prescribe.

(10) [~~(6)~~] Enrollee--As defined in Insurance Code §1369.051(2) [~~Article 21.52J~~].

(11) [~~(7)~~] Health [~~Group health~~] benefit plan--An insurance policy or evidence of coverage as [~~As~~] described in Insurance Code §1369.052, but not those described in Insurance Code §1369.053, that provides coverage for a discrete package of benefits, paired with specific cost-sharing parameters [~~Article 21.52J~~]. This term includes [~~group~~] health benefit plans providing coverage for pharmacy benefits only.

(12) [~~(8)~~] Issuer--Those entities described [~~identified~~] in Insurance Code §1369.052, but not those excluded by Insurance Code §1369.053 [~~Article 21.52J, Sec. 2(a)(1) (8)~~].

(13) [~~(9)~~] Multitier [~~Multi-tier~~] formulary--A drug formulary with benefit levels in addition to generic and brand name prescription drug benefit levels.

(14) Off-label drug use--The use of a drug that is approved by the Food and Drug Administration for the treatment of one medical condition but is used to treat another medical condition, or at different dosage forms, dosage regimens, populations, or other parameters not mentioned in the approved labeling.

(15) [~~(10)~~] Plain language--As prescribed in §3.602 of this title (relating to Plain Language Requirements).

(16) [~~(11)~~] Plan year--A 365-day period that begins on the date the [~~group~~] health benefit plan's coverage commences, or a period of one full calendar year as defined in the [~~group~~] health benefit plan's coverage documentation.

(17) [~~(12)~~] Prescription drug--As defined in Insurance Code §1369.051(4) [~~Article 21.52J~~].

(18) [~~(13)~~] Renewal date--For each [~~group~~] health benefit plan, the earlier of the date specified in the coverage documentation for renewal or the policy anniversary date. In determining the renewal date for association or multiple employer trust [~~group~~] health benefit plans, issuers may use the

date specified for renewal or the policy anniversary date of either the master contract, plan document, or certificate of coverage of each group in the association or trust. Issuers must [~~shall~~] use the same method of determining renewal dates for all [~~group~~] health benefit plans.

(19) Summary health plan document--A document summarizing the coverage provided under a health benefit plan, including:

(A) a summary of benefits and coverage, as required under 42 U.S.C. §300gg-15 and 45 CFR §147.200; and

(B) a disclosure of terms and conditions of a policy, as required under §3.3705(b) of this title (relating to Nature of Communications with Insureds; Readability, Mandatory Disclosure Requirements, and Plan Designations), or an evidence of coverage, as required under §11.1600(b) of this title (relating to Information to Prospective and Current Contract Holders and Enrollees).

§21.3022. Continuation of Benefits.

(a) An issuer of a [~~group~~] health benefit plan that offers prescription drug benefits must [~~shall~~] make a prescription drug that was approved or covered for a medical condition or mental illness available to each enrollee at the contracted benefit level until the [~~group~~] health benefit plan renewal date [~~, regardless of whether the prescribed drug has been removed from the group health benefit plan's drug formulary~~]. Modifications to drug coverage are not permitted until the plan's renewal date.

(b) A health benefit plan issuer may make modifications to drug coverage provided under a health benefit plan if:

(1) the modification occurs at the time of coverage renewal;

(2) the modification is effective uniformly among all group health benefit plan sponsors covered by identical or substantially identical health benefit plans, or all individuals covered by identical or substantially identical individual health benefit plans, as applicable; and

(3) not later than the 60th day before the date the modification is effective, the issuer provides written notice of the modification to the commissioner, each affected group health benefit plan sponsor, each affected enrollee in an affected group health benefit plan, and each affected individual health benefit plan holder.

(c) For the purposes of this section, modifications to drug coverage include:

(1) removing a drug from a formulary;

(2) adding a requirement that an enrollee receive prior authorization for a drug;

(3) imposing or altering a quantity limit for a drug;

(4) imposing a step-therapy restriction for a drug; and

(5) moving a drug to a higher cost-sharing tier unless a generic drug alternative is available.

[~~(b) Continuation of benefits for those group health benefit plans that utilize a multi-tier formulary, regardless of whether the prescription drug has been moved to another formulary tier, shall be the same as that specified in subsection (a) of this section.~~]

[~~(c) An issuer of a group health benefit plan, or its delegated entity, that provides coverage for prescription drugs, and did not utilize a multi-tier formulary at the beginning of the plan year, but which later adopts a multi-tier formulary, shall continue to make a prescription drug that was approved or covered for a medical condition or a mental illness, available to each enrollee at the same contracted benefit level before the multi-tier formulary was adopted, until the group health benefit plan's renewal date.~~]

§21.3023. Nonformulary Prescription Drugs; Adverse Determination.

If the issuer of a [~~group~~] health benefit plan, its delegated entity, or their employees or agents refuses to provide coverage for a prescription drug that is not included in a drug formulary, and the enrollee's physician or other health care provider with prescriptive authority has determined the prescription drug is medically necessary to treat a condition covered by the enrollee's [~~group~~] health benefit plan, the refusal to provide coverage for the prescription drug constitutes an adverse determination for the purpose of Insurance Code Chapter 4201 [~~Article 21.58A, §2~~]. An enrollee may appeal the adverse determination under Insurance Code Chapter 4201, Subchapters H and I [~~Article 21.58A, §§6 and 6A~~], and the issuer of the [~~group~~] health benefit plan, and its employees or agents, must [~~shall~~] review and resolve the appeal in accordance with those sections.

§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 a 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 and Facilitating Comparison Shopping) 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 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 on Issuer's Website.

(a) Except as permitted under subsection (c) of this section, an issuer of a health benefit plan must display the formulary information required under §21.3032 and §21.3033 of this title (relating to Formulary Disclosure Requirements and Facilitating Comparison Shopping) 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, a 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 the amount of the applicable deductible;

(B) the full price of the drug, based on the plan's median allowed amount for the drug using the most up-to-date data available;

(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-administered setting, if applicable, after the enrollee has met 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;

(4) include, prominently displayed on the web page under the header "Formulary by Health Benefit Plan," a direct electronic link to a chart displaying each formulary that applies to each 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.

(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 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 that limits access to the drug; 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 the amount of the applicable deductible;

(2) the cost-sharing amount for each drug under the pharmacy or medical benefit, in a retail, mail order, or physician-administered setting, if applicable, after the enrollee has met 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 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.

(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.

(a) The formulary information 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 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 after meeting any applicable deductible, calculated using an estimate of the full price of the drug, which is based on the plan's median 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 health benefit plan issued by the issuer and includes a direct electronic link to the Summary of Benefits and Coverage 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.

(3) Under the header, "Drugs by Cost-Sharing Tier," if the drug formulary is a multitier formulary, a summary that displays for all drugs in the formulary:

(A) the total number of drugs in each cost-sharing tier; and

(B) the percent of drugs in each cost-sharing tier.

(4) Under the header, "Coverage for Commonly Prescribed Drugs":

(A) the percent of the drugs contained on the commonly prescribed drug list that are included in the formulary as covered, as of the date the information is provided, accompanied by the label, "Percent of Commonly Prescribed Drugs Included in this Plan," separately specifying:

(i) the percent of drugs contained on the commonly prescribed drug list that are covered without prior authorization, step therapy, or other protocol requirements that limit

access to prescription drugs, accompanied by the label, "Percent of Commonly Prescribed Drugs Covered NOT Subject to Medical Management Requirements," and;

(ii) the percent of drugs contained on the commonly prescribed drug list that are covered subject to prior authorization, step therapy, or other protocol requirements that limit access to prescription drugs, accompanied by the label, "Percent of Commonly Prescribed Drugs Covered Subject to Medical Management Requirements";

(B) the percent of drugs contained on the commonly prescribed drug list that are not covered in the formulary, accompanied by the label, "Percent of Commonly Prescribed Drugs NOT Included in this Plan."

(5) 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, if 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 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."

§21.3034. Effective Date.

(a) The requirements under §§21.3030 - 21.3033 of this title (relating to Availability of Formulary Information, Formulary Disclosure Requirements, and Facilitating Comparison Shopping) are effective

for plans marketed in the individual market on or after November 1, 2016, with an effective date on or after January 1, 2017.

(b) The requirements under §§21.3030 - 21.3033 of this title are effective for plans marketed in the group market on or after September 1, 2017.

STATUTORY AUTHORITY. The repeal of §21.3005 and §21.3021 is proposed under Insurance Code §§1369.052, 1369.054, 1369.057, 1369.154 and 36.001. Section 1369.052 extends the applicability of Subchapter B to individual, small group, and large group health benefit plans; §1369.054 provides the notice and disclosure of certain information required by issuers of a health benefit plan that covers prescription drugs and uses one or more drug formularies to specify the prescription drugs covered under the plan; §1369.057 provides that the commissioner may adopt rules to implement Chapter 1369, Subchapter B; §1369.154 provides that the commissioner may adopt rules to implement Chapter 1369, Subchapter D; and §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. The proposed repeal of §21.3005 and §21.3021 affect the following statutes: Insurance Code §§36.001, 1369.052, 1369.054, 1369.057, and 1369.154.

SUBCHAPTER V. PHARMACY BENEFITS

§21.3005. Previously Issued Identification Cards.

§21.3021. Required Disclosure of Drug Formulary.

CERTIFICATION. This agency 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 January 12, 2016.

Norma Garcia
General Counsel
Texas Department of Insurance