SUBCHAPTER V. PHARMACY BENEFITS
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REPEAL OF §21.3005 and §21.3021

INTRODUCTION. The Texas Department of Insurance adopts amendments to 28 TAC Chapter 21, Subchapter V, relating to Pharmacy Benefits, §§21.3001 - 21.3004, 21.3010, 21.3011, and 21.3023; repeals §21.3005 and §21.3021; and it adds new §21.3030 without changes from the proposal that was published in the February 5, 2016, issue of the *Texas Register* (41 TexReg 917). TDI adopts amendments to §21.3020 and §21.3022, and it adds new §§21.3031 - 21.3034 with nonsubstantive changes to the text as proposed.

REASONED JUSTIFICATION.

HB 1624, 84th Legislature, Regular Session (2015) 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 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 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 for 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. 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 a specific plan 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.

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 adoption 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.

Amendments.

The amendments to §§21.3001 - 21.3004, 21.3010, 21.3011, and 21.3023 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 amendments to §21.3020 add terms, and the amendments to §21.3022 clarify notice of modifications to drug coverage.

An amendment conforms §21.3002(7) to Insurance Code §1369.151, which states the subchapter is applicable to state employees, Medicaid, and the Child Health Insurance Program (CHIP) plans. Another amendment conforms §21.3003 to Insurance Code §1369.153, which designates the information that must be located on the front and back of an enrollee's identification card. An amendment conforms the term "health benefit plan" in §21.3020(10) 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 that it is not applicable to CHIP and Medicaid Managed Care Organizations, respectively. An amendment conforms §21.3022 to Insurance Code §1369.0541, which specifies conditions under which modifications of drug coverage may occur and adds notice requirements.

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of §21.3005 is necessary because it applies to identification cards that were in effect on September 1, 1999, and it is no longer applicable.

The repeal of §21.3021 streamlines the rules implementing Insurance Code Subchapter B. The requirements contained in §21.3021 are included in §21.3030(a) to implement Insurance Code §1369.054.

New §§21.3030 - 21.3034 implement the portions of HB 1624, 84th Legislature, Regular Session (2015) 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, and make the information available to enrollees, prospective enrollees, and others through a toll-free telephone number.

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 does not include §21.3005, as that section is repealed. New Division 3, titled "Off-Label Drugs," encompasses existing §21.3010 and §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, 21.3022, and 21.3023, relating to continuation of benefits and adverse determination of nonformulary prescription drugs, and new §§21.3030 - 21.3034, relating to required drug formulary disclosures. Division 4 does not include §21.3021, as that section is repealed. The provisions contained in repealed §21.3021 are incorporated in §21.3030(a).

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 amendments also contain conforming changes for clarity and agency style, and to update Insurance Code citations.

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

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

§21.3002. Definitions; Pharmacy Identification Cards. The 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 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," so 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 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 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 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 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 amendment to current §21.3003(b)(6) moves the text to 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 amendment 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.

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. Amendments to §21.3004(c) - (d) remove references to §21.3005, as this adoption repeals §21.3005.

§21.3005. Previously Issued Identification Cards. Section 21.3005 is repealed because both subsections of §21.3005 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. Amendments to §21.3010 make changes for clarity, to conform to agency style, and to update Insurance Code citations.

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

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

An amendment to §21.3020 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.

The new term, "allowed amount," is added to §21.3020(2) and is defined 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, payments, or coinsurance."

In response to comments, the proposed term, "commonly prescribed drug list," defined 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," is removed from the requirements of §21.3033.

The definition of "delegated entity" clarifies that third-party administrators are those defined in Insurance Code §4151.001(1) and pharmacy benefits are those defined in Insurance Code §4151.151.

The term, "direct electronic link," is defined as "a hyperlink that, when clicked, delivers a user directly to the applicable website destination."

The term, "drug," is added and defined by referencing the term in the Texas Pharmacy Act, Occupations Code §551.003.

The definition for "drug formulary or formulary" is clarified on adoption in response to comment to exclude open formularies. The definition states that "This term does not include a health benefit plan that: (A) offers coverage for any FDA-approved drug; (B) does not include a tiered structure; (C) does not contain a list of drugs; and (D) does not include utilization requirements for particular drugs or classes of drugs. This removes the requirements for an open formulary to comply with this division.

Amendments to current "health group benefit plan" 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.

The term, "off-label drug use," is added and defined 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."

The term, "summary health plan document," is added and defined 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)."

The definitions are redesignated to conform to the changes.

§21.3021. Required Disclosure of Drug Formulary. The repeal of §21.3021 is necessary 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. Amendments to §21.3022 remove the word, "group," preceding "health benefit plan," for consistency with Insurance Code §1369.052.

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 amendment to §21.3022(a) clarifies that modifications to drug coverage are not permitted until the plan's renewal date. The 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. In response to comments, TDI moved the substance of proposed subsection (c) to subsection (b) to clarify the text regarding the modifications that require notice. Also in response to comments, TDI created new subsection (c), which allows modifications more favorable to the consumer to be made without notice and at any time, including the addition of drugs to formularies, a reduction in cost sharing, or the deletion of utilization management requirements.

§21.3023. Nonformulary Prescription Drugs; Adverse Determination. Amendments to §21.3023 correct typographical, grammatical, and punctuation errors; make changes to conform to agency 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. 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. New §21.3030(b) requires an issuer of a health benefit

plan to make a paper copy of the formulary information required under new §21.3032 and §21.3033, available to a current or prospective enrollee on request. 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. New §21.3030(d) requires the paper copy to use at least 10-point font.

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

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. New §21.3031(a)(1) - (2) state that formulary information must be electronically searchable by drug name and use at least 10-point font.

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.

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). 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.

In response to comments, TDI has removed the requirement for the formulary information to state the amount of the deductible in §21.3031(c)(3)(B), but adds that the formulary information must state where the deductible can be found.

In response to a comment suggesting that using the actual cost of the drug would be more feasible than the median for drug calculation purposes, TDI revises §21.3031(c)(3)(B) to adopt an alternative option. The health benefit plan issuer has the choice to provide the actual cost or median,

but the rules require that the information be identified as either actual cost or median so that the option being used is clear to the consumer.

To clarify §21.3031(c)(3)(C), the proposed language has been changed from the cost-sharing amount to be calculated "after the enrollee has met any deductible requirement," to "excluding any deductible requirement."

Section 21.3031(c)(4) requires that the web 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. The 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. 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 it specifies that the information must differentiate between drugs covered under the plan's pharmacy benefits and medical benefits. In response to a comment, the word, "direct electronic link," was added to this subsection so that the last sentence now reads: "Information pertaining to drugs covered under the plan's medical benefits may be provided as an addendum or direct electronic link and must include each parameter that is applicable." This clarifies that a link is the electronic equivalent of an addendum.

New §21.3032(b)(1) - (4) describe the coverage information that must be included for each drug. In response to a comment, the phrase "that limits access to the drug" has been removed from the disclosure "of any prior authorization, step therapy, or other protocol requirement," because the phrase is unnecessary.

New §21.3032(c) requires the formulary information to include plan-specific cost-sharing information for each drug. New §21.3032(c)(1) requires the formulary information to indicate whether the drug is subject to a pharmacy or medical deductible. In response to comments, TDI has removed the requirement for the formulary information to state the amount of the deductible, but adds that the formulary information must state where the deductible can be found.

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- or practitioner-

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

In response to a comment, the "practitioner-administered" setting was added to the physician-administered setting. For clarity, the proposed language has been changed from the cost-sharing amount to be calculated "after the enrollee has met any deductible requirement," to "excluding any deductible requirement."

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.

In response to a comment suggesting that using the actual cost of the drug would be more feasible than the median for drug calculation purposes, TDI adopts an alternative option. The formulary information may provide the actual cost or median, but the rule requires that the information be identified as either actual cost or median so that the option being used is clear to the consumer.

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

§21.3033. Facilitating Comparison Shopping. 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 by one plan to those offered by other plans. 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. A citation is added to the language for clarity.

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.

For clarity, the proposed language has been changed from the cost-sharing amount to be calculated "after the enrollee has met any deductible requirement," to "excluding any deductible requirement." In response to a comment suggesting that using the actual cost of the drug would be more feasible, TDI adopts an alternative option. The formulary information may provide the actual cost

or median, but the rule requires that the information be identified as either actual cost or median so that option being used is clear to the consumer.

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.

New §21.3033(a)(3) requires a section in the summary titled "Drugs by Cost-Sharing Tier."

In response to comments, TDI removed the proposed requirement for a list of total number of drugs because it was not informative. TDI retains the requirement for the percent of drugs in each cost-sharing tier for all drugs in the formulary.

The proposed new §21.3033(a)(4) titled "Coverage for Commonly Prescribed Drugs," is deleted. The proposal included a requirement for information on coverage for commonly prescribed drugs for comparison purposes. In response to comments, this paragraph is not included in the adopted rule, deleting the requirement that prices be compared to the New York List of Commonly Prescribed Drugs.

The next paragraph is redesignated §21.3033(a)(4). It requires a section in the summary titled "How Prescription Drugs are Covered under the Plan," to include information on how prescription drugs are covered under the plan. New §21.3033(a)(4)(A) - (F) describe the information an issuer must include in the summary.

New §21.3033(a)(4)(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.

New §21.3033(a)(4)(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.

New §21.3033(a)(4)(C) requires a section in the summary titled "Continuation of Coverage," which explains the consumer's right to continued coverage consistent with amended §21.3022 and Insurance Code §1369.055 and §1369.0541.

New §21.3033(a)(4)(D) requires a section in the summary titled "Off-Label Drug Use," which explains coverage for off-label drug use.

New §21.3033(a)(4)(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.

New §21.3033(a)(4)(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.

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

§21.3034. Effective Date. In response to comments, another subsection is added to this section. Subsection (a) extends the effective date of the changes to the identification cards under §§21.3002 - 21.3004 of this title (relating to Definitions; Pharmacy Identification Cards, Standard Identification Cards, and Issuance of Standard Identification Cards) to January 1, 2017. Subsection (a) is redesignated as subsection (b). It states the effective dates of new §§21.3030 - 21.3033 for plans being marketed in the individual market. Subsection (b) is redesignated as subsection (c) and states the effective dates of new §§21.3030 - 21.3033 for plans being marketed in the group market.

SUMMARY OF COMMENTS AND AGENCY RESPONSE. A hearing was held on February 24, 2016, and oral and written comments were received. Comments were received from the Coalition for Nurses in Advanced Practice; Office of Public Insurance Counsel; Pharmaceutical Care Management Association; American Cancer Society Cancer Action Network, Inc.; Prime Therapeutics; Center for Public Policy Priorities; America's Health Insurance Plans; Texas Association of Health Plans; and the National Multiple Sclerosis Society.

Comment: Regarding §21.3003, one commenter stated that the front of the identification card is getting crowded.

Agency Response: The requirement to place "TDI" or "DOI" on the front of the card is already required under §21.2820; the addition of §21.3003 is intended to simplify compliance by locating all requirements for pharmacy ID cards in one section of the code. The other content requirements for the front of the card are required by Insurance Code §1369.153. However, TDI has revised §21.3034 to move the effective date of this requirement to January 1, 2017.

Comment: Regarding §21.3020, one commenter stated that the definition for "summary health plan document," should not specifically incorporate federal requirements, which are subject to change.

Agency Response: TDI disagrees with the comment and declines to make a change. The definition incorporates the statutory requirement at TIC §1369.0542(b), requiring issuers to include a link to the formulary information from the summary of benefits and coverage. If the requirements change, the definition will also change.

Comment: Regarding §21.3021, one commenter stated that they were pleased to see the dollar amount rather that the dollar range required in the web tool and for the cost-sharing amount after meeting the deductible. The commenter pointed out that the predeductible and postdeductible cost of prescription drugs is important to consumers.

Another commenter supported both web-based tool and online formulary to provide information on the dollar cost, including coinsurance.

Agency Response: TDI appreciates the supportive comments.

Comment: Regarding §21.3022, one commenter interpreted the proposed rule to allow mid-year modifications if moving a drug to a higher cost-sharing tier if there is a generic drug available, although the statute only allows modifications at renewal. Another commenter suggested the rule should prohibit a plan from moving a drug to a higher cost-sharing tier midyear if a generic is available.

A third commenter acknowledged that the renewal date in the proposed rule conformed to statute, but emphasized the need for flexibility in formula modifications.

Two commenters stated that formularies are updated during the year to include the release of new prescription drugs and to update usage warnings or FDA notices to discontinue use. The commenters stated they would like to be able to move a brand-name drug to a higher-cost tier if a generic is released midyear. Both entities consider only allowing modifications on the plan's renewal date to be administratively unmanageable because plans become effective and expire at different times of the year. Restricting formulary changes limits the plans' abilities to mitigate the excessive price hikes by drug manufacturers. One commenter pointed out that prohibiting the movement of brand-names to a higher tier when generics are available hurts businesses and consumers.

Agency Response: TDI disagrees with the comments and has revised the rule text to provide clarification.

Insurance Code §1369.0541 only authorizes modifications of drug coverage on the plan's renewal date. The "at the time of coverage renewal" language has existed in the statute since 2011. The language in subsection (b)(5) referencing moving a drug to a higher cost-sharing tier if there is a generic drug available concerns whether notice must be given when coverage is modified at renewal under subsection (a) and does not permit that type of change to be accomplished midyear. TDI has clarified this in the rule text.

Doctors must use their judgment about whether to prescribe drugs if the FDA has withdrawn approval or the drugs have been recalled. TDI has revised the rule so that modifications more favorable to the consumer may be made without notice and at any time, including the addition of drugs to formularies, a reduction in cost sharing, or the deletion of utilization management requirements. The legislative history of HB 1405, 82nd Legislature, Regular Session (2011) demonstrates that the intent of the bill was to prevent occurrences that were detrimental to the consumer such as increasing the cost of a drug or dropping a drug altogether, before the renewal date.

Comment: Regarding §21.3030, two commenters pointed out a typographical error referencing §21.3032(c), formulary information on issuer's website, when it should have referenced §21.3032(c), formulary disclosure requirements.

One commenter also recommended that plans provide a statement clearly explaining that consumers can obtain actual drug cost-sharing information by calling the toll-free number.

Another commenter suggested that there be a direct link to either the web tool or formulary that includes cost-sharing information with the toll-free number on every page of the mailed copy.

Agency Response: TDI agrees with the comment regarding a typographical error, and the change has been made regarding the citation.

TDI disagrees with the recommendations regarding an additional statement and the toll-free number. An additional statement would be an additional cost to the insurer and thus, cannot be made at this time. Notice of the toll-free number is available in the summary health plan document. An issuer has the option of providing a direct link to the web tool or formulary. Adding a requirement for the toll-free number on every page of the mailed copy would be an additional cost.

Comment: Regarding §21.3031(a), one commenter supported the drug coverage information being available to enrollees and potential enrollees. The commenter stated the online tool and formulary is very important to cancer patients, especially being able to see what their coinsurance means as far as out-of-pocket costs.

Regarding §21.3031(b), another commenter supported language that requires a direct link to the formulary information. It supported the web-based tool language, and points out that some health plans are already providing drug cost information via web tools, and health plans are already providing postdeductible cost-sharing information to their members.

Agency Response: TDI appreciates the supportive comments.

Comment: Regarding §21.3031(c)(3)(A), a commenter stated that the information provided should describe whether the drug is subject to a pharmacy or medical deductible, not the actual deductible.

Agency Response: TDI agrees with the commenter and has revised the proposed text. TDI has removed the requirement to state the actual deductible. TDI has added that the web-based tool must indicate where that deductible can be found, so that consumers can find it in their plan documents.

Comment: Regarding §21.3031(c)(3)(B), a commenter stated that the rule should not specify that the cost-sharing amount be rounded to the next highest dollar because some plans may be able to calculate specific amounts without rounding, and some may prefer to round down as appropriate. The commenter said the median is not feasible because the contracts are not based on the simple monetary

amount for each drug, but rather are often tied to Maximum Allowable Cost pricing, average wholesale pricing, etc.

Another commenter suggested that the wording regarding "the full price of the drug" in subsection §21.3031(c)(3)(B) and (c)(3)(C)(ii) be changed because although the commenter thinks the median price is reasonable, if it is not feasible then TDI should consider using a different definition for full cost that is consistent across carriers.

Agency Response: TDI agrees in part with the commenters and has added an alternative option in the text as adopted to address these concerns. The health benefit plan issuer has the choice whether to provide the exact cost-sharing amount or round up. This issuer also has the choice whether to provide the actual cost or median, but the rules require that the information be identified as either actual cost or median so that option is clear to the consumer. Subsection (c)(3)(C) is also changed to clarify that cost-sharing information is required excluding any deductible requirements.

Comment: Regarding §21.3031(c)(3)(c) and §21.3032(c)(2), a commenter stated that the phrase "physician-administered setting" should include other practitioners or providers who may legally prescribe in Texas. The commenter suggested revising the term so that it reads "physician- or practitioner-administered setting."

In both §21.3031 and §21.3032, another commenter indicated support for the requirement that information covered under both medical and pharmacy benefits be shared; and asked that plan specificity, including the amount of the copayment and amount or range of coinsurance after the deductible, be retained in the rule.

In both §21.3031 and §21.3032, a third commenter stated that they consider the statute to require a description of the deductible, but not the actual deductible. The commenter expressed concern that calculating for each deductible will be very complex. The commenter asked that the disclosure assume 100 percent enrollee cost sharing.

Agency Response: TDI agrees with the comments in part and has made the change to "physician- or practitioner-administered setting." TDI has eliminated the actual deductible language, but retains the requirements addressing cost sharing as it relates to copayments and coinsurance excluding the deductible. Taking the deductible out of the calculation should reduce the complexity of the different products. A 100 percent cost sharing would be 100 percent of the negotiated price; this does not give

the necessary copay and coinsurance dollar amounts. Some plans already provide the copay and coinsurance amounts for existing enrollees.

Comment: Regarding §21.3032(a), a commenter commended TDI for requiring that coverage and cost information for drugs covered under a plan's medical benefit be included in the formulary information. The commenter added that many cancer treatment medications are administered intravenously by a provider. Another commenter stated that including the medical benefit will greatly benefit consumers who receive provider-administered drugs.

Another commenter stated their support that the information for prescription drugs covered both medical and pharmacy, and found providing drugs covered under medical benefits as an addendum acceptable. The commenter suggested that if the direct link takes you to the pharmacy drug list and the addendum is located elsewhere, TDI should require information about the separate addendum, including where to find it and how to use it.

A third commenter stated that because costs are not tied to pharmacy rates and the benefits are considered to be medical rather than pharmacy benefits, that the medical drug coverage is not part of a formulary. The commenter stated that providing cost-sharing and other information will be more complex and take longer to implement. The commenter also stated that it would be more feasible and informative to provide general information regarding application of deductibles to prescription drug benefits, and that calculation of the drug cost sharing is difficult.

Agency Response: TDI appreciates the supportive comments and agrees to revise the section to provide additional clarification. Insurance Code Chapter 1369 Subchapter B specifically applies to drugs dispensed in a pharmacy and to those typically administered by a physician or provider. The proposal delayed the effective date of this part of the rule until November 1, 2016. TDI will limit the requirement to an amount excluding the deductible requirement. This significantly reduces the complexity of the algorithm.

The words "direct electronic link" was added to §21.3032(a), so that the last sentence is, "Information pertaining to drugs covered under the plan's medical benefits may be provided as an addendum or direct electronic link to the formulary and must include each parameter that is applicable." This clarifies that a link is the electronic equivalent of an addendum.

Comment: Regarding 21.3032(b), one commenter stated they were not opposed to disclosures of prior authorization requirements, but found the characterization of prior authorization to be unnecessary and potentially misleading.

Agency Response: TDI agrees that the verbiage "limiting access," as it refers to prior authorization, is unnecessary. However, the term "other protocol requirement," should be interpreted to mean any plan provision that limits access to a formulary drug, regardless of whether limiting access is the primary intent of the provision.

Comment: Regarding §21.3032(c) and (d), four commenters stated that the calculation related to the postdeductible amounts would be very complex because of the variety of benefit designs. One of the commenters estimated that it would have to customize over 1,700 formularies. The commenters added that the complexity of separately postdeductible cost sharing will take years, millions of dollars to implement, and the calculations would require hundreds of pages. One commenter stated that it has over 4,000 pages for open formularies.

Another commenter estimates a build out would cost $3 million even if the rule is delayed to November 2017. The commenter stated that they do not want to pass these costs onto consumers. Another commenter stated that including all drugs within an open formulary creates a technical challenge and provides little benefit to the consumer. This is especially difficult for the medical drugs because they are not considered part of the formulary. The commenter adds that since they are a pharmacy benefit manager, they do not have access to medical drug pricing.

Another commenter supports the option for carriers to disclose patient costs in online formulary documents, specifically in dollar costs or a dollar cost range.

Agency Response: TDI disagrees with the comments and declines to change the requirement for cost-sharing information. The requirement for cost-sharing information cannot be changed because Insurance Code §1369.0543(d)(1) requires "the dollar amount of a copayment," and "an enrollee's cost-sharing amount stated in dollars." The web tool requirement in Insurance Code §1369.0543(e) provides for a search for drug information "by the name under which the health benefit plan is marketed."

However, TDI adopts §21.3032(c) and (d) with changes so that the cost-sharing amount can be calculated as if there is not a deductible. Regarding open formularies, the definition of “drug formulary” in Insurance Code §1369.051 references a “list” of covered drugs. In light of the comment, TDI has

modified the definition of "drug formulary" in §21.3020 to make it clear that the rule does not apply to a true open formulary which does not list, tier, or restrict access to covered drugs. This reduces the complexity of the calculation. Regarding access to medical drug pricing, although one commenter may not have access to the information as a pharmacy benefit manager, it is working with an issuer that has that information.

Comment: A commenter stated that for the group fully insured market, the rule would require a long list of plans and associated formularies and summary-of-benefits links that would not be available to the consumer.
Agency Response: TDI disagrees with the comment and declines to make a change. In this case, the consumer is the employer. The statute does not exempt group plans.

Comment: Regarding §21.3032(e), a commenter asked that the legend be added to the web tool. Another commenter supports the use of a legend to make disclosures more consumer friendly.
Agency Response: TDI agrees that the legend will be useful for consumers, but does not think a change is necessary. The wording of §21.3032(e) requires a legend whether it is on the website or on paper.

Comment: Regarding §21.3033, two commenters stated that having the total number of drugs and each cost-sharing amount will not help with comparison shopping. They stated that providing the information is likely to be more confusing than helpful to consumers because it would not account for generics versus brand-name drugs, different dosages available, etc. In addition, displaying the long list of plans and formulas for the group fully insured market could add confusion for the consumers because it could lead to consumers reviewing information that is not applicable to their plan. One of the commenters stated that most consumers shop primarily on premium rates.

Another commenter appreciated having all the information in one place when comparison shopping. The commenter added that complexity of understanding formulary costs and the personal costs that come with choosing the wrong plan are borne by consumers today. This shifts some of that burden from consumers to insurers and pharmacy benefits managers who are better equipped to efficiently compile this information.

Agency Response: TDI agrees to revise the text as adopted to avoid confusion for consumers. The adopted rules delete the requirement to list the total number of drugs, but retains the requirement to list the percent of drugs in each cost-sharing tier. TDI agrees that having all the information in one place is beneficial to consumers.

Comment: One commenter said they anticipate that §21.3033 will be extremely helpful to Texas consumers. It will help consumers who are shopping for the most comprehensive prescription drug cover and those consumers living with a chronic illness. People living with multiple sclerosis may also develop other conditions. Although it may be challenging for health plans and pharmacy benefit managers, it should not be the consumer's burden to piece together information from several sources. The commenter believes that creating consistent headings and a consistent order for information will help consumers when comparing formularies, but notes that under the header, "How to Find Information on the Cost of Prescription Drugs" in §21.3033(a)(1), an addendum with medical-benefit drugs should be included.
Agency Response: TDI agrees with the commenter. The addendum should include the medical drugs under §21.3032(a).

Comment: Regarding §21.3033(a)(2), one commenter would like a clearly marked link to the chart from the disclosure and web tool.
Agency Response: TDI does not agree that a revisions is necessary to address the commenter’s concern. The Summary of Formulary Benefits, including the chart, is required to be included as part of the formulary disclosure document under §21.3033(b). The web tool is required to link to the chart under §21.3031(c)(4).

Comment: Regarding §21.3033(a)(4), two commenters stated they were unable to find any evidence that consumers use a list like the New York list when deciding which company to choose. The rules infer that reduced management is a greater value; this minimizes the value of safety and efficacy oversight. The New York List of Commonly Prescribed Drugs is not meaningful, is confusing, and does not provide much value. Another commenter suggested the alternative of providing drugs by drug class.

Agency Response: TDI agrees to revise the rule text as adopted to address the commenters' concern. The adopted rules remove the comparison to the New York list. Providing information only by drug class would be too general.

Comment: Three commenters urged TDI not to implement product disclosures that go beyond the federal regulations. Specifically, a commenter asked TDI to delete the requirement that paper copies of formularies would have to calculate the cost to the enrollee in dollar amounts of each covered drug based on their benefit plan cost sharing and deductible.

Another commenter expressed concern that requiring more detailed information than what is required under federal regulations will make the consumer research and shopping experiences overwhelming and confusing. The commenter added that these disclosures may not be seen by consumers who work directly with the online shopping sites or exchanges and brokers or agents, which could add unnecessary costs and confusion to the health care system.

Agency Response: TDI disagrees with the commenters and declines to make the requested change. Insurance Code §1369.0543 requires TDI to go beyond the federal requirements. Calculations will be made as if there is no deductible, which reduces the complexity of the calculations. In addition, publishing the information on the website will greatly reduce the requests for paper copies.

Comment: Regarding §21.3033(a)(4), one commenter stated that §21.3033(a)(4) included an excessive list of additional disclosures that are redundant or unnecessary.

Agency Response: TDI disagrees with the commenter and declines to revise the provision. This paragraph standardizes important information and places it in one area to provide consistency and clarity.

Comment: Regarding §21.3034, two commenters indicated that they would like to see the individual market rules take effect when proposed so the information is available during the next open enrollment period.

Another commenter requested that TDI take into consideration the complexity of the new requirements and extend the effective date appropriately. The commenter requested that the changes to the identification cards be effective January 1, 2017, or after.

Agency Response: TDI agrees with the first two commenters regarding a need for the rules to be effective for the individual market during the next open enrollment period. HB 1624, 84th Legislature, Regular Session, (2015), was passed in May 2015. TDI is extending the effective date for the group market until September 2017. The effective date for the individual market needs to be before the next enrollment period.

In response to the third commenter, TDI agrees to extend the effective date for the changes to identification cards. TDI is adding a subsection to §21.3034 that extends the effective date for the identification cards to January 1, 2017.

Text

SUBCHAPTER V. PHARMACY BENEFITS
DIVISION 1. GENERAL PROVISIONS
28 TAC §21.3001

STATUTORY AUTHORITY. The amendments to §21.3001 are adopted 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. Section 1369.057 provides that the commissioner may adopt rules to implement Insurance Code Chapter 1369, Subchapter B. Section 1369.151 extends the applicability of Insurance Code Chapter 1369, Subchapter D, to include state employee, Medicaid, and CHIP plans. Section 1369.154 provides that the commissioner may adopt rules to implement Insurance Code Chapter 1369, Subchapter D. Section 36.001 provides that the commissioner may adopt any rules necessary and appropriate to implement the powers and duties of TDI under the Insurance Code and other laws of this state.

CROSS REFERENCE TO STATUTE. The 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 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.

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

SUBCHAPTER V. PHARMACY BENEFITS
DIVISION 2. IDENTIFICATION CARDS
28 TAC §§21.3002 - 21.3004

STATUTORY AUTHORITY. The amendments to §§21.3002 - 21.3004 are adopted under Insurance Code §§843.209, 1369.052, 1369.151, 1369.153, 1369.154, 1301.162, and 36.001.

Section 843.209 requires that HMO identification cards indicate that the HMO is regulated under Insurance Code. Section 1369.052 extends the applicability of Subchapter B to individual, small group, and large group health benefit plans. Section 1369.151 extends the applicability of Insurance Code Chapter 1369, Subchapter D, to include state employee, Medicaid, and CHIP plans. Section 1369.153 designates identification card content that must be located on the front of the card. Section 1369.154 provides that the commissioner may adopt rules to implement Chapter 1369, Subchapter D. Section 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. Section 36.001 provides that the

commissioner may adopt any rules necessary and appropriate to implement the powers and duties of TDI under the Insurance Code and other laws of this state.

DIVISION 2. IDENTIFICATION CARDS

§21.3002. Definitions; Pharmacy Identification Cards.

The following words and terms when used in this division 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.

(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, 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), but does not include a self-funded employee welfare benefit plan exempt from state regulation under ERISA, 29 U.S.C. §1002(1)(A).

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

(9) Issuer--Those entities described in Insurance Code §1369.151, but not those excluded by Insurance Code §1369.152.

(10) Pharmacy benefit manager--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).

(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 (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 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 issue standard identification cards as follows:

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

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

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

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

(3) For coverage under an individual health benefit plan in which the subscriber is not an enrollee, or for coverage under a health benefit plan that is continued by an enrollee under Insurance Code Chapter 1251, Subchapter E, either:

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

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

(b) Each standard identification card issued must, 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 cards issued under subsection (a)(1) of this section, the enrolled subscriber's name and identification code;

(B) for cards issued under 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 cards issued under subsection (a)(2)(B) of this section, the name and identification code of the enrolled subscriber and the names and identification codes of all the enrolled dependents;

(D) for cards issued under 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 cards issued under subsection (a)(3)(B) of this section, the names and identification codes of all enrolled dependents;

(2) 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) 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) the effective date of coverage;

(5) 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 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;

(6) 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) 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 (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 (relating to Standard Identification Cards); and

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

(b) Under 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 enter into an agreement as to which entity will issue the standard identification card in accordance with this subchapter.

(c) If 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 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 the health benefit plan that the enrollee is eligible for the pharmacy benefits.

(d) If the issuer of a health benefit plan is required to issue a standard identification card, the issuer of the health benefit plan must 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 adopted under Insurance Code §§1369.004, 1369.005, and 36.001.

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. Section 1369.005 provides that the commissioner may adopt rules to implement Insurance Code Chapter 1369, Subchapter A. Section 36.001 provides that the commissioner may adopt any rules necessary and appropriate to implement the powers and duties of TDI under the Insurance Code and other laws of this state.

CROSS REFERENCE TO STATUTE. The amendments to §21.3010 and §21.3011 affect the following statutes: Insurance Code §§1369.001(1) and (3), 1369.002, 1369.004, 1369.005, and 36.001.

DIVISION 3. OFF-LABEL DRUGS

§21.3010. Definitions; Coverage of Off-Label Drugs. The following words and terms, when used in this division 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).

(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, 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. 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).

(10) Issuer--Those entities described in Insurance Code §1369.002, but not those excluded by Insurance Code §1369.003.

(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 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 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 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 it is medically necessary for an off-label use, the refusal constitutes an adverse determination for purposes of Insurance Code

§4201.002(1). An enrollee may appeal the adverse determination under Insurance Code Chapter 4201, Subchapters H and I;

(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, and 21.3023; and new §§21.3030 - 21.3034 are adopted under Insurance Code §§1369.005, 1369.052 - 1369.054, 1369.0541 - 1369.0544, 1369.055 - 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. Section 1369.052 extends the applicability of Subchapter B to individual, small group, and large group health benefit plans. Section 1369.053 provides exceptions to the applicability of Insurance Code Chapter 1369 Subchapter B, and it exempts CHIP and Medicaid Managed Care Organizations. Section §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. Section 1369.0541 specifies conditions under which modifications of drug coverage may occur and creates notice requirements. Section 1369.0542 requires a health benefit plan issuer to post formulary information on its website as required by the commissioner by rule. Section 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. Section 1369.0544 allows a health benefit plan issuer to make the formulary information available through a toll-free telephone number. Section 1369.055 describes the continuation of drug coverage requirements an issuer of a health benefit plan must offer if prescription drugs are covered. Section

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. Section 1369.057 provides that the commissioner may adopt rules to implement Insurance Code Chapter 1369, Subchapter B. Section 1369.151 extends the applicability of Insurance Code Chapter 1369, Subchapter D, to include state employee, Medicaid, and CHIP plans. Section 1369.154 provides that the commissioner may adopt rules to implement Insurance Code Chapter 1369, Subchapter D. Section 36.001 provides that the commissioner may adopt any rules necessary and appropriate to implement the powers and duties of TDI under the Insurance Code and other laws of this state.

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 have the following meanings, unless the context clearly indicates otherwise:

(1) Adverse determination--As defined in Insurance Code §4201.002.

(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) Contracted benefit level--The copayment amount or coinsurance percentage established at the beginning of the current plan year and described in the coverage documentation.

(4) 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.

(5) Delegated entity--An entity or an association of entities, including 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 provides reimbursement for covered services or undertakes to arrange for or provide benefits or services to an enrollee under a health benefit plan, and that performs on behalf of the issuer of a health benefit plan, any function regulated by this division.

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

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

(8) 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. This term does not include a health benefit plan that:

(A) offers coverage for any FDA approved drug;

(B) does not include a tiered structure;

(C) does not contain a list of drugs; and

(D) does not include utilization requirements for particular drugs or classes of drugs.

(9) Enrollee--As defined in Insurance Code §1369.051(2).

(10) Health benefit plan--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. This term includes health benefit plans providing coverage for pharmacy benefits only.

(11) Issuer--Those entities described in Insurance Code §1369.052, but not those excluded by Insurance Code §1369.053.

(12) Multitier formulary--A drug formulary with benefit levels in addition to generic and brand-name prescription drug benefit levels.

(13) 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.

(14) Plain language--As prescribed in §3.602 of this title (relating to Plain Language Requirements).

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

(16) Prescription drug--As defined in Insurance Code §1369.051(4).

(17) Renewal date--For each 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 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 use the same method of determining renewal dates for all health benefit plans.

(18) 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 health benefit plan that offers prescription drug benefits must 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 health benefit plan renewal date. 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 for modifications that:

(A) remove a drug from a formulary;

(B) add a requirement that an enrollee receive prior authorization for a drug;

(C) impose or alter a quantity limit for a drug;

(D) impose a step-therapy restriction for a drug; or

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

(c) For purposes of this section, modifications that are more favorable to the consumer may be made without notice at any time, including modifications that:

(1) add drugs to formularies;

(2) reduce cost sharing; or

(3) delete a utilization review requirement.

§21.3023. Nonformulary Prescription Drugs; Adverse Determination. If the issuer of a health benefit plan, its delegated entity, or its 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 health benefit plan, the refusal to provide coverage for the prescription drug constitutes an adverse determination for the purpose of Insurance Code Chapter 4201. An enrollee may appeal the adverse determination under Insurance Code Chapter 4201, Subchapters H and I, and the issuer of the health benefit plan, and its employees or agents, must 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 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 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 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.

(a) The formulary information required by §21.3032 of this title (relating to Formulary Disclosure Requirements) 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 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 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 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 §§21.3002 - 21.3004 of this title (relating to Definitions; Pharmacy Identification Cards, Standard Identification Cards, and Issuance of Standard Identification Cards) are effective January 1, 2017.

(b) 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.

(c) 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.

SUBCHAPTER V. PHARMACY BENEFITS
28 TAC §21.3005 AND §21.3021

STATUTORY AUTHORITY. The repeal of §21.3005 and §21.3021 is adopted 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. Section 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. Section 1369.057 provides that the commissioner may adopt rules to implement Chapter 1369, Subchapter B. Section §1369.154 provides that the commissioner may adopt rules to implement Chapter 1369, Subchapter D. Section 36.001 provides that the commissioner may adopt any rules necessary and appropriate to implement the powers and duties of TDI under the Insurance Code and other laws of this state.

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 new and amended sections and repeal, and found them to be a valid exercise of the agency's legal authority.

Issued at Austin, Texas, on July 28, 2016.

Norma Garcia
General Counsel
Texas Department of Insurance

The commissioner adopts new and amended 28 TAC Subchapter V. Division 1. §21.3001; Division 2. §§21.3002 - 21.3004; Division 3. §21.3010 and §21.3011; Division 4. §§21.3020, 21.3022, 21.3023, and 21.3030 - 21.3034; and the repeal of §21.3005 and §21.3021.

David C. Mattax
Commissioner of Insurance

COMMISSIONER' S ORDER NO. **4605**