

ADOPTED RULES

Adopted rules include new rules, amendments to existing rules, and repeals of existing rules. A rule adopted by a state agency takes effect 20 days after the date on which it is filed with the Secretary of State unless a later date is required by statute or specified in the rule (Government Code, §2001.036). If a rule is adopted without change to the text of the proposed rule, then the *Texas Register* does not republish the rule text here. If a rule is adopted with change to the text of the proposed rule, then the final rule text is included here. The final rule text will appear in the Texas Administrative Code on the effective date.

TITLE 4. AGRICULTURE

PART 1. TEXAS DEPARTMENT OF AGRICULTURE

CHAPTER 1. GENERAL PROCEDURES SUBCHAPTER G. INTERAGENCY AGREEMENTS

4 TAC §1.330

The Texas Department of Agriculture (Department) adopts the repeal of 4 Texas Administrative Code, Chapter 1, §1.330. The repeal is adopted without changes to the proposed text as published in the July 16, 2021, issue of the *Texas Register* (46 TexReg 4254). The repeal will not be republished.

The repeal is in response to Senate Bill (SB) 703, 87th Legislature, Regular Session (2021), which among other things, eliminates the Department's Aquaculture program. SB 703, Sections 35 and 57 deletes the Department's authority to enter into a memorandum of understanding relating to aquaculture facilities with the Texas Commission on Environmental Quality and the Texas Department of Parks and Wildlife, and requires the repeal of all rules relating to a license issued under Texas Agriculture Code, §§134.011 and 134.012, respectively.

The Department received no comments on the proposed repeal.

The repeal is adopted under Section 12.016 of the Texas Agriculture Code (Code), which provides that the Department may adopt rules as necessary for the administration of its powers and duties under the Code; Section 134.005 of the Code, which provides that the Department shall adopt rules to carry out its duties under Chapter 134 of the Code; and Section 2001.006 of the Texas Government Code, which provides a state agency with the authority to take administrative action in preparation for the implementation of legislation that has become law, but has not taken effect.

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

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CHAPTER 7. PESTICIDES

SUBCHAPTER C. LICENSING

4 TAC §7.21

The Texas Department of Agriculture (the Department) adopts an amendment to Texas Administrative Code, Title 4, Part 1, Chapter 7, Subchapter C, Licensing, §7.21. The amendment is adopted without changes to the proposed text as published in the May 28, 2021, issue of the *Texas Register* (46 TexReg 3343). The rule will not be republished. The amendment is adopted under Texas Agriculture Code, Chapter 76, as amended by Senate Bill (SB) 1312, 86th Legislature, Regular Session, 2019. SB 1312 mandated the issuance of a noncommercial applicator license that authorizes a person to purchase and use restricted-use and state-limited-use pesticides for the limited purpose of mosquito control in a county located along the international border with Mexico.

The adopted amendment to §7.21 establishes category definitions and defined use-sites for noncommercial political license use category for which the department is responsible. The adopted amendment defines and establishes a new category to certify an applicator in border mosquito control, category 13.

The Department received no comments on the proposed amendment.

Statutory Authority

The amendment is adopted under Section 76.1095 of the Texas Agriculture Code, which provides the Department by rule shall provide for the issuance of a noncommercial applicator license that authorizes a person to purchase and use restricted-use and state-limited-use pesticides for the limited purpose of mosquito control in a county located along the international border with Mexico.

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

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CHAPTER 16. AQUACULTURE

4 TAC §§16.1 - 16.3

The Texas Department of Agriculture (Department) adopts the repeal of rules at 4 Texas Administrative Code, Chapter 16, §§16.1 - 16.3, regarding Aquaculture. The repeals are adopted without changes to the proposed text as published in the July 16, 2021, issue of the *Texas Register* (46 TexReg 4255). These repeals will not be republished.

The repeals are in response to Senate Bill (SB) 703, 87th Legislature, Regular Session (2021), which among other things, eliminates the Department's Aquaculture program. SB 703, Section 57 requires the repeal of all rules relating to a license issued under Texas Agriculture Code, §§134.011 and 134.012.

The Department received no comments on the proposed repeals.

The repeals are adopted under Section 12.016 of the Texas Agriculture Code (Code), which provides that the Department may adopt rules as necessary for the administration of its powers and duties under the Code; Section 134.005 of the Code, which provides that the Department shall adopt rules to carry out its duties under Chapter 134 of the Code; and Section 2001.006 of the Texas Government Code, which provides a state agency with the authority to take administrative action in preparation for the implementation of legislation that has become law, but has not taken effect.

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

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TITLE 19. EDUCATION

PART 2. TEXAS EDUCATION AGENCY

CHAPTER 30. ADMINISTRATION

SUBCHAPTER AA. COMMISSIONER OF EDUCATION: GENERAL PROVISIONS

19 TAC §30.1001

The Texas Education Agency (TEA) adopts an amendment to §30.1001, concerning petitioning for the adoption of rule changes. The amendment is adopted without changes to the proposed text as published in the July 2, 2021 issue of the *Texas Register* (46 TexReg 4019) and will not be republished. The adopted amendment updates the commissioner of education's petition procedures to allow for electronic submission of a petition authorized under Texas Government Code (TGC), §2001.021.

REASONED JUSTIFICATION: TGC, §2001.021, requires that procedures to petition for the adoption of rule changes be adopted by rule. To comply with statute, the commissioner adopted §30.1001 effective September 23, 2004. Effective May 12, 2009, an amendment adopted in rule the petition form to be used to submit a petition. Effective April 26, 2017, an amendment updated the petition form adopted in rule to require the petitioner to indicate that the petitioner meets one of the four definitions of an interested person specified in statute and added language to specify the reasons the commissioner may deny a petition for rulemaking.

The adopted amendment to §30.1001 updates the commissioner's petition procedures, including the petition form included as Figure: 19 TAC §30.1001(a), to improve efficiency by ensuring that an interested person can submit the petition for rulemaking electronically. In addition, the adopted amendment to Figure: 19 TAC §30.1001(a) specifies one Texas Education Agency (TEA) division as the collection point for all petitions submitted to the commissioner. This will ensure timely acknowledgement and reviewing of a petition by TEA staff for consideration by the commissioner.

The adopted amendment to §30.1001(a) also adds the term "Texas Education Agency" to make it clear that this petition procedure applies to rules that TEA adopts.

The adopted amendment to §30.1001(b) and (c) replaces "commissioner" with "TEA staff" to reflect that the initial review of the merits of the petition is conducted by TEA staff for recommendation to the commissioner.

The adopted amendment to §30.1001(c) adds "calendar" to the phrase "60 days" to clarify the timeline for responding to a petition.

In addition, the adopted amendment to §30.1001(d)(4)(A) clarifies that the commissioner may deny a petition if the petition is filed within one year of the commissioner denying a petition on a similar rule or the same subject matter. This change addresses similar or duplicate petitions submitted within one year. The time period of one year was already established in rule and was not proposed to be changed.

The adopted amendment also includes technical edits throughout §30.1001 to improve readability.

SUMMARY OF COMMENTS AND AGENCY RESPONSES: The public comment period on the proposal began July 2, 2021, and ended August 2, 2021. No public comments were received.

STATUTORY AUTHORITY. The amendment is adopted under Texas Government Code, §2001.021, which authorizes a state agency to prescribe by rule the form for a petition and the procedure for the submission, consideration, and disposition.

CROSS REFERENCE TO STATUTE. The amendment implements Texas Government Code, §2001.021.

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

Filed with the Office of the Secretary of State on August 23, 2021.

TRD-202103291



CHAPTER 97. PLANNING AND ACCOUNTABILITY

SUBCHAPTER AA. ACCOUNTABILITY AND PERFORMANCE MONITORING

19 TAC §97.1005

The Texas Education Agency (TEA) adopts an amendment to §97.1005, concerning results driven accountability (RDA). The amendment is adopted without changes to the proposed text as published in the June 25, 2021 issue of the *Texas Register* (46 TexReg 3807) and will not be republished. The amendment adopts in rule the 2021 RDA Manual.

REASONED JUSTIFICATION: House Bill 3459, 78th Texas Legislature, 2003, added Texas Education Code (TEC), §7.027, limiting and redirecting monitoring done by TEA to that required to ensure school district and charter school compliance with federal law and regulations; financial accountability, including compliance with grant requirements; and data integrity for purposes of the Texas Student Data System (TSDS) PEIMS and accountability under TEC, Chapter 39. Legislation passed in 2005 renumbered TEC, §7.027, to TEC, §7.028. To meet this monitoring requirement, TEA developed the Performance Based Monitoring Analysis System (PBMAS), later renamed as RD in 2019, which is used in conjunction with other evaluation systems to monitor performance of certain populations of students and the program effectiveness of special programs in school districts and charter schools.

TEA adopted its PBMAS Manual in rule from 2005 through 2018 and the RDA Manual in rule since 2019. The RDA Manual outlines a dynamic system that evolves over time, so the specific criteria and calculations for monitoring student performance and program effectiveness may differ from year to year. The intent is to update §97.1005 annually to refer to the most recently published RDA Manual.

The adopted amendment to §97.1005 updates the current rule by adopting the 2021 RDA Manual, which describes the specific criteria and calculations that will be used to assign 2021 RDA performance levels, as Figure: 19 TAC §97.1005(b).

The 2021 RDA Manual includes the following key changes from the 2020 system.

Referenced dates relevant to the 2021 RDA indicator data and calculations are updated throughout. Additional explanatory text is added to the RDA Manual overview as well as exemplar data for calculation methodologies demonstration.

Bilingual Education, English as a Second Language, and English Learner (BE/ESL/EL)

New report only indicators are included for BE/ESL/EL Indicator #1(i-v): BE STAAR2 3-8 Passing Rate; and BE/ESL/EL Indicator #2(i-v): ESL STAAR 3-8 Passing Rate due to lack of comparable year data with included data sets for setting cut-point param-

eters. A new indicator named BE/ESL/EL Indicator #5(i-v): EL Years-After-Reclassification (YsAR) STAAR 3-8 Passing Rate is included to parallel with programmatic terminology usage only with no impacts to data inclusion or exclusion. Duplicative information and renumeration of data notes are eliminated.

Other Special Populations (OSP)

Changes to this section include only minor language clean-up with no changes to reporting.

Special Education (SPED)

Indicator analysis and reporting is expanded for SPED Indicator #5: SPED STAAR Alternate 2 Participation Rate (by race/ethnicity, data source).

Of Note for all RDA Program Areas

On March 16, 2020, Governor Greg Abbott waived the State of Texas Assessment of Academic Readiness (STAAR®) testing requirements for the 2019-2020 school year due to extensive school closures relating to the COVID-19 nationwide pandemic event. As a result, indicators specific to STAAR® testing proficiency, participation, or other reliance on non-existing 2019-2020 STAAR® data were assigned an "ND" for no data availability for RDA in 2020. Because application of the Special Analysis (SA) process uses data over the prior two years, impacted STAAR® assessment indicators will not include SA processing for RDA in 2021.

SUMMARY OF COMMENTS AND AGENCY RESPONSES: The public comment period on the proposal began June 25, 2021, and ended July 26, 2021. Following is a summary of the public comment received and corresponding response.

Comment: An individual expressed concerns regarding declines in participation rates and STAAR® results relating to school closures and quarantines and recommended that all STAAR® indicators be report only without performance level assignment until LEAs are able to make up compensatory services and allow student achievement to recover.

Response: The agency disagrees with the recommended change to the 2021 RDA Manual and reports. TEA is responsible for implementing *Guiding Principles of the RDA*, including *Principle 2: Drives Improved Results and High Expectations* for identified special student populations and for complying with monitoring requirements described in 34 Code of Federal Regulations, §300.600, specifically for students with disabilities. TEA recognizes the commentor's concern for COVID-19 impacts on student attendance and proficiency results that are measured on the RDA LEA reports. However, RDA results are used by the agency as one part of its RDA Framework in TEA's annual evaluation of student performance and program effectiveness resulting in overall determinations of LEA need. Measuring STAAR® available data allows for differentiated support to LEAs in their efforts to recover student achievement slippage.

STATUTORY AUTHORITY. The amendment is adopted under Texas Education Code (TEC), §7.021(b)(1), which authorizes the Texas Education Agency (TEA) to administer and monitor compliance with education programs required by federal or state law, including federal funding and state funding for those programs; TEC, §7.028, which authorizes TEA to monitor as necessary to ensure school district and charter school compliance with federal law and regulations, financial integrity and data integrity. Section 7.028(a) also authorizes TEA to monitor special education programs for compliance with state and federal laws.

Section 7.028 also authorizes the agency to monitor school district and charter schools through its investigative process; TEC, §12.056, which requires that a campus or program for which a charter is granted under TEC, Chapter 12, Subchapter C, is subject to any prohibition relating to the Public Education Information Management System (PEIMS) to the extent necessary to monitor compliance with TEC, Chapter 12, Subchapter C, as determined by the commissioner; high school graduation under TEC, §28.025; special education programs under TEC, Chapter 29, Subchapter A; bilingual education under TEC, Chapter 29, Subchapter B; and public school accountability under TEC, Chapter 39, Subchapters B, C, D, F, and J, and Chapter 39A; TEC, §12.104, which states that a charter granted under TEC, Chapter 12, Subchapter D, is subject to a prohibition, restriction, or requirement, as applicable, imposed by TEC, Title 2, or a rule adopted under TEC, Title 2, relating to PEIMS to the extent necessary to monitor compliance with TEC, Chapter 12, Subchapter D, as determined by the commissioner; high school graduation requirements under TEC, §28.025; special education programs under TEC, Chapter 29, Subchapter A; bilingual education under TEC, Chapter 29, Subchapter B; discipline management practices or behavior management techniques under TEC, §37.0021; public school accountability under TEC, Chapter 39, Subchapters B, C, D, F, G, and J, and Chapter 39A; and intensive programs of instruction under TEC, §28.0213; TEC, §29.001, which authorizes TEA to effectively monitor all local educational agencies (LEAs) to ensure that rules relating to the delivery of services to children with disabilities are applied in a consistent and uniform manner, to ensure that LEAs are complying with those rules, and to ensure that specific reports filed by LEAs are accurate and complete; TEC, §29.0011(b), which authorizes TEA to meet the requirements under (1) 20 United States Code, §1418(d), and its implementing regulations to collect and examine data to determine whether significant disproportionality based on race or ethnicity is occurring in the state and in the school districts and open-enrollment charter schools in the state with respect to the: (A) Identification of children as children with disabilities, including the identification of children as children with particular impairments; (B) Placement of children with disabilities in particular educational settings; and (C) Incidence, duration, and type of disciplinary actions taken against children with disabilities including suspensions or expulsions; or (2) 20 United States Code, §1416(a)(3)(C), and its implementing regulations to address in the statewide plan the percentage of schools with disproportionate representation of racial and ethnic groups in special education and related services and in specific disability categories that results from inappropriate identification; TEC, §29.010(a), which authorizes TEA to adopt and implement a comprehensive system for monitoring LEA compliance with federal and state laws relating to special education, including ongoing analysis of LEA special education data; TEC, §29.062, which authorizes TEA to evaluate and monitor the effectiveness of LEA programs and apply sanctions concerning students with limited English proficiency; TEC, §29.066, which authorizes PEIMS reporting requirements for school districts that are required to offer bilingual education or special language programs to include the following information in the district's PEIMS report: (1) demographic information, as determined by the commissioner, on students enrolled in district bilingual education or special language programs; (2) the number and percentage of students enrolled in each instructional model of a bilingual education or special language program offered by the district; and (3) the number and percentage of students identified as students of limited English proficiency

who do not receive specialized instruction; TEC, §29.182, which authorizes the State Plan for Career and Technology Education to ensure the state complies with requirements for supplemental federal career and technology funding; TEC, §39.051 and §39.052, which authorize the commissioner to determine criteria for accreditation statuses and to determine the accreditation status of each school district and open-enrollment charter school; TEC, §39.053, which authorizes the commissioner to adopt a set of indicators of the quality of learning and achievement and requires the commissioner to periodically review the indicators for consideration of appropriate revisions; TEC, §39.054(b-1), which authorizes TEA to consider the effectiveness of district programs for special populations when determining accreditation statuses; TEC, §39.0541, which authorizes the commissioner to adopt indicators and standards under TEC, Chapter 39, Subchapter C, at any time during a school year before the evaluation of a school district or campus; TEC, §§39.056, 39.057, and 39.058, which authorize the commissioner to adopt procedures relating to monitoring reviews and special accreditation investigations; TEC, §39A.001, which authorizes the commissioner to take any of the actions authorized by TEC, Chapter 39, Subchapter A, to the extent the commissioner determines necessary if a school does not satisfy the academic performance standards under TEC, §39.053 or §39.054, or based upon a special accreditation investigation; TEC, §39A.002, which authorizes the commissioner to take certain actions if a school district becomes subject to commissioner action under TEC, §39A.001; TEC, §39A.004, which authorizes the commissioner to appoint a board of managers to exercise the powers and duties of a school district's board of trustees if the district is subject to commissioner action under TEC, §39A.001, and has a current accreditation status of accredited-warned or accredited-probation; or fails to satisfy any standard under TEC, §39.054(e); or fails to satisfy any financial accountability standard; TEC, §39A.005, which authorizes the commissioner to revoke school accreditation if the district is subject to TEC, §39A.001, and for two consecutive school years has received an accreditation status of accredited-warned or accredited-probation, failed to satisfy any standard under TEC, §39.054(e), or has failed to satisfy a financial performance standard; TEC, §39A.007, which authorizes the commissioner to impose a sanction designed to improve high school completion rates if the district has failed to satisfy any standard under TEC, §39.054(e), due to high school completion rates; TEC, §39A.051, which authorizes the commissioner to take action based on campus performance that is below any standard under TEC, §39.054(e); and TEC, §39A.063, which authorizes the commissioner to accept substantially similar intervention measures as required by federal accountability measures in compliance with TEC, Chapter 39A.

CROSS REFERENCE TO STATUTE. The amendment implements Texas Education Code, §§7.021(b)(1), 7.028, 12.056, 12.104, 29.001, 29.0011(b), 29.010(a), 29.062, 29.066, 29.182, 39.051, 39.052, 39.053, 39.054(b-1), 39.0541, 39.056, 39.057, 39.058, 39A.001, 39A.002, 39A.004, 39A.005, 39A.007, 39A.051, and 39A.063.

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

Filed with the Office of the Secretary of State on August 20, 2021.

TRD-202103287



CHAPTER 151. COMMISSIONER'S RULES CONCERNING PASSING STANDARDS FOR EDUCATOR CERTIFICATION EXAMINATIONS

19 TAC §151.1001

The Texas Education Agency (TEA) adopts an amendment to §151.1001, concerning passing standards for educator certification examinations. The amendment is adopted without changes to the proposed text as published in the May 14, 2021 issue of the *Texas Register* (46 TexReg 3115) and will not be republished. The adopted amendment specifies the satisfactory scores for the following educator certification examinations: Science of Teaching Reading, Early Childhood: PK-3, English Language Arts and Reading 4-8, Educational Diagnostician, and Principal as Instructional Leader.

REASONED JUSTIFICATION: Texas Education Code, §21.048(a), requires the commissioner of education to establish the satisfactory levels of performance required on educator certification examinations and require a satisfactory level of performance on each core subject covered by an examination.

The amendment adopts passing standards for the Science of Teaching Reading, Early Childhood: PK-3, English Language Arts and Reading 4-8, Educational Diagnostician, and Principal as Instructional Leader examinations.

A standard setting committee of educators developed recommended passing standards for the Science of Teaching Reading, Early Childhood: PK-3, Principal as Instructional Leader, and Educational Diagnostician examinations. The adopted amendment to §151.1001(b)(1) implements passing standards one standard error measurement (SEM) below the committee-recommended passing standard for both the selected-response and constructed-response sections of the Science of Teaching Reading and Early Childhood: PK-3 examinations. The adopted amendment to §151.1001(c) implements passing standards one SEM below the committee-recommended passing standard for both the selected-response and constructed-response sections of the Educational Diagnostician examination. The adopted amendment to §151.1001(d) implements a passing standard for the selected-response section of the Principal as Instructional Leader examination one-half SEM below the committee-recommended passing standard and a passing standard for the constructed-response section of the Principal as Instructional Leader examination one SEM below the committee-recommended passing standard. The intent of implementing passing standards one-half or one SEM below the committee-recommended passing standards is to support the transition to implementation of new educator certification examinations.

The adopted amendment to §151.1001(b)(2) implements initial passing standards for the English Language Arts and Reading 4-8 examination. The initial passing standards include the passing standard for selected-response and constructed-response

examination sections. During the introductory period, the initial passing standard for the constructed-response section of each examination will be "complete." The adopted amendment defines "complete" as a full and complete scorable response that must address the specific requirements of the item, be of sufficient length to respond to the requirements of the item, be original work and written in the candidate's own words (however, candidates may use citations when appropriate), and conform to the standards of written English. The use of "complete" as the passing standard will allow candidates and programs the opportunity to become familiar with the new examination before facing a rigorous passing standard and thereby support the transition to implementation of the new English Language Arts and Reading 4-8 examination.

The initial passing standards for the English Language Arts and Reading 4-8 examination adopted under §151.1001(b)(2) will be implemented during an eight-month introductory period. This introductory period will provide candidates and educator preparation programs with a transition period to adjust to a more rigorous examination and allow for the collection of examination performance data to inform the development of passing standards for both the selected-response and constructed-response sections after the introductory period. Standard setting committees for this examination will develop recommendations to be used to develop passing standards after the introductory period. The initial passing standards for English Language Arts and Reading 4-8 will be implemented prior to September 5, 2022.

SUMMARY OF COMMENTS AND AGENCY RESPONSES: The public comment period on the proposal began May 14, 2021, and ended June 14, 2021. No public comments were received.

STATUTORY AUTHORITY. The amendment is adopted under Texas Education Code, §21.048(a), which requires the commissioner to determine the level of performance considered to be satisfactory on educator certification examinations and further authorizes the commissioner to require a satisfactory level of performance on each core subject covered by an examination.

CROSS REFERENCE TO STATUTE. The amendment implements Texas Education Code, §21.048(a).

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

Filed with the Office of the Secretary of State on August 17, 2021.

TRD-202103216

Cristina De La Fuente-Valadez

Director, Rulemaking

Texas Education Agency

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TITLE 22. EXAMINING BOARDS

PART 8. TEXAS APPRAISER LICENSING AND CERTIFICATION BOARD

CHAPTER 153. RULES RELATING TO PROVISIONS OF THE TEXAS APPRAISER LICENSING AND CERTIFICATION ACT

22 TAC §153.8

The Texas Appraiser Licensing and Certification Board (TALCB) adopts amendments to §153.8, Scope of Practice, without changes to the proposed text as published in the May 28, 2021, issue of the *Texas Register* (46 TexReg 3357). The rule will not be republished.

The amendments implement changes adopted by the Appraiser Qualifications Board (AQB) which became effective on January 1, 2021. The change was based on federal law which increased the threshold for residential real estate transactions requiring an appraisal from \$250,000 to \$400,000. The amendments increase the transaction threshold for licensed residential appraisers from \$250,000 to \$400,000 to align TALCB rules with AQB requirements and federal law.

No comments were received on the amendments as published.

The amendments are adopted under Texas Occupations Code §1103.151, which authorizes TALCB to adopt rules related to certificates and licenses that are consistent with applicable federal law and guidelines adopted by the AQB.

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

Filed with the Office of the Secretary of State on August 23, 2021.

TRD-202103293

Kathleen Santos

General Counsel

Texas Appraiser Licensing and Certification Board

Effective date: September 12, 2021

Proposal publication date: May 28, 2021

For further information, please call: (512) 936-3652



22 TAC §153.21

The Texas Appraiser Licensing and Certification Board (TALCB) adopts amendments to §153.21, Appraiser Trainees and Supervisory Appraisers, without changes to the proposed text, as published in the May 28, 2021, issue of the *Texas Register* (46 TexReg 3358). The rule will not be republished.

The amendments clarify rules related to qualification requirements for supervisory appraisers as adopted by the Appraiser Qualifications Board (AQB). To be eligible to supervise an appraiser trainee, a certified appraiser must not have had practice-interrupting discipline in the prior three years. The amendments clarify that this only applies to disciplinary actions. Administrative actions do not prohibit an appraiser from acting as a supervisor.

No comments were received on the amendments as published.

The amendments are adopted under Texas Occupations Code §1103.151, which authorizes TALCB to adopt rules related to certificates and licenses that are consistent with applicable federal law and guidelines adopted by the AQB.

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

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TRD-202103294

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Proposal publication date: May 28, 2021

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PART 15. TEXAS STATE BOARD OF PHARMACY

CHAPTER 283. LICENSING REQUIREMENTS FOR PHARMACISTS

22 TAC §283.4

The Texas State Board of Pharmacy adopts amendments to §283.4, concerning Internship Requirements. These amendments are adopted without changes to the proposed text as published in the June 25, 2021, issue of the *Texas Register* (46 TexReg 3810). The rule will not be republished.

The amendments update the internship hours requirement to reflect that the board requires the number of intern hours required by the Accreditation Council for Pharmacy Education (ACPE).

No comments were received.

The amendments are adopted under §§551.002 and 554.051 of the Texas Pharmacy Act (Chapters 551 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by this adoption: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

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

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TRD-202103280

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Texas State Board of Pharmacy

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Proposal publication date: June 25, 2021

For further information, please call: (512) 305-8010



CHAPTER 291. PHARMACIES SUBCHAPTER A. ALL CLASSES OF PHARMACIES

22 TAC §291.6

The Texas State Board of Pharmacy adopts amendments to §291.6, concerning Pharmacy License Fees. These amendments are adopted with changes to the proposed text as published in the June 25, 2021, issue of the *Texas Register* (46 TexReg 3813). The Board adjusted the amount of the fees based on updated information. The rule will be republished.

The amendments increase pharmacy license fees based on expected expenses.

No comments were received.

The amendments are adopted under §§551.002 and 554.051 of the Texas Pharmacy Act (Chapters 551 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by this adoption: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

§291.6. Pharmacy License Fees.

(a) Initial License Fee. The fee for an initial license shall be \$516 for the initial registration period.

(b) Biennial License Renewal. The Texas State Board of Pharmacy shall require biennial renewal of all pharmacy licenses provided under the Act §561.002.

(c) Renewal Fee. The fee for biennial renewal of a pharmacy license shall be \$513 for the renewal period.

(d) Duplicate or Amended Certificates. The fee for issuance of a duplicate pharmacy license renewal certificate shall be \$20. The fee for issuance of an amended pharmacy license renewal certificate shall be \$100.

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

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Texas State Board of Pharmacy

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Proposal publication date: June 25, 2021

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SUBCHAPTER D. INSTITUTIONAL PHARMACY (CLASS C)

22 TAC §291.76

The Texas State Board of Pharmacy adopts amendments to §291.76, concerning Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center. These amendments are adopted with changes to the proposed text as published in the June 25, 2021, issue of the *Texas Register* (46 TexReg 3814). The rule will be republished.

The amendments allow a licensed nurse who is authorized by the pharmacist to perform the loading of an automated medication supply system; update the time interval in which a pharmacist must verify a drug withdrawal; update the requirements for using a floor stock method of drug distribution; update records requirements; and correct grammatical errors.

The Board received a comment from Lisa Walker, R.Ph., in support of the amendment to remove the language allowing a medication order in a patient's chart to substitute for the record of withdrawal of a drug or device in the absence of a pharmacist to restock a floor stock area, expressing concern about the amendment to require an ASC pharmacy with a part-time or consultant pharmacist to make a record of withdrawal of a drug or device from the pharmacy in the absence of a pharmacist for administration to a patient, and suggested limiting the rule to only require a record of withdrawal for controlled substances removed from the pharmacy pursuant to a medication order. The Board declines to make this change.

The Board received a comment jointly submitted by Christopher M. Dembny, Joseph Staller, Jeff Neale, Beto Quezada, Libby Gibbs, Lisa Walker, Julie Sifford, and Jerry Jackson, R.Ph.s., in support of the amendment to allow a licensed nurse authorized by a pharmacist to perform the loading of an automated medication supply system and expressing concern about the amendment to require an ASC pharmacy with a part-time or consultant pharmacist to make a record of withdrawal of a drug or device from the pharmacy in the absence of a pharmacist for administration to a patient.

The Board received a comment from the Texas Ambulatory Surgery Center Society in support of the amendment to allow a licensed nurse authorized by a pharmacist to perform the loading of an automated medication supply system and expressing concern about the amendment to remove the language allowing a medication order in a patient's chart to substitute for the record of withdrawal of a drug or device in the absence of a pharmacist to restock a floor stock area. The Board agreed and did not remove the language allowing a medication order in a patient's chart to substitute for the record of withdrawal of a drug or device in the absence of a pharmacist to restock a floor stock area.

The amendments are adopted under §§551.002 and 554.051 of the Texas Pharmacy Act (Chapters 551 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by this adoption: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

§291.76. Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center.

(a) Purpose. The purpose of this section is to provide standards in the conduct, practice activities, and operation of a pharmacy located in a freestanding ambulatory surgical center that is licensed by the Texas Department of State Health Services. Class C pharmacies located in a freestanding ambulatory surgical center shall comply with this section, in lieu of §§291.71 - 291.75 of this title (relating to Purpose; Definitions; Personnel; Operational Standards; and Records).

(b) Definitions. The following words and terms, when used in these sections, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Act--The Texas Pharmacy Act, Occupations Code, Subtitle J, as amended.

(2) Administer--The direct application of a prescription drug by injection, inhalation, ingestion, or any other means to the body of a patient by:

(A) a practitioner, an authorized agent under his supervision, or other person authorized by law; or

(B) the patient at the direction of a practitioner.

(3) Ambulatory surgical center (ASC)--A freestanding facility that is licensed by the Texas Department of State Health Services that primarily provides surgical services to patients who do not require overnight hospitalization or extensive recovery, convalescent time or observation. The planned total length of stay for an ASC patient shall not exceed 23 hours. Patient stays of greater than 23 hours shall be the result of an unanticipated medical condition and shall occur infrequently. The 23-hour period begins with the induction of anesthesia.

(4) Automated medication supply system--A mechanical system that performs operations or activities relative to the storage and distribution of medications for administration and which collects, controls, and maintains all transaction information.

(5) Board--The Texas State Board of Pharmacy.

(6) Consultant pharmacist--A pharmacist retained by a facility on a routine basis to consult with the ASC in areas that pertain to the practice of pharmacy.

(7) Controlled substance--A drug, immediate precursor, or other substance listed in Schedules I - V or Penalty Groups 1 - 4 of the Texas Controlled Substances Act, as amended, or a drug immediate precursor, or other substance included in Schedules I - V of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended (Public Law 91-513).

(8) Dispense--Preparing, packaging, compounding, or labeling for delivery a prescription drug or device in the course of professional practice to an ultimate user or his agent by or pursuant to the lawful order of a practitioner.

(9) Distribute--The delivery of a prescription drug or device other than by administering or dispensing.

(10) Downtime--Period of time during which a data processing system is not operable.

(11) Electronic signature--A unique security code or other identifier which specifically identifies the person entering information into a data processing system. A facility which utilizes electronic signatures must:

(A) maintain a permanent list of the unique security codes assigned to persons authorized to use the data processing system; and

(B) have an ongoing security program which is capable of identifying misuse and/or unauthorized use of electronic signatures.

(12) Floor stock--Prescription drugs or devices not labeled for a specific patient and maintained at a nursing station or other ASC department (excluding the pharmacy) for the purpose of administration to a patient of the ASC.

(13) Formulary--List of drugs approved for use in the ASC by an appropriate committee of the ambulatory surgical center.

(14) Hard copy--A physical document that is readable without the use of a special device (i.e., data processing system, computer, etc.).

(15) Investigational new drug--New drug intended for investigational use by experts qualified to evaluate the safety and effectiveness of the drug as authorized by the federal Food and Drug Administration.

(16) Medication order--An order from a practitioner or his authorized agent for administration of a drug or device.

(17) Pharmacist-in-charge--Pharmacist designated on a pharmacy license as the pharmacist who has the authority or responsibility for a pharmacy's compliance with laws and rules pertaining to the practice of pharmacy.

(18) Pharmacy--Area or areas in a facility, separate from patient care areas, where drugs are stored, bulk compounded, delivered, compounded, dispensed, and/or distributed to other areas or departments of the ASC, or dispensed to an ultimate user or his or her agent.

(19) Prescription drug--

(A) A substance for which federal or state law requires a prescription before it may be legally dispensed to the public;

(B) A drug or device that under federal law is required, prior to being dispensed or delivered, to be labeled with either of the following statements:

(i) Caution: federal law prohibits dispensing without prescription or "Rx only" or another legend that complies with federal law; or

(ii) Caution: federal law restricts this drug to use by or on order of a licensed veterinarian; or

(C) A drug or device that is required by any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by a practitioner only.

(20) Prescription drug order--

(A) An order from a practitioner or his authorized agent to a pharmacist for a drug or device to be dispensed; or

(B) An order pursuant to Subtitle B, Chapter 157, Occupations Code.

(21) Full-time pharmacist--A pharmacist who works in a pharmacy from 30 to 40 hours per week or if the pharmacy is open less than 60 hours per week, one-half of the time the pharmacy is open.

(22) Part-time pharmacist--A pharmacist who works less than full-time.

(23) Pharmacy technician--An individual who is registered with the board as a pharmacy technician and whose responsibility in a pharmacy is to provide technical services that do not require professional judgment regarding preparing and distributing drugs and who works under the direct supervision of and is responsible to a pharmacist.

(24) Pharmacy technician trainee--An individual who is registered with the board as a pharmacy technician trainee and is authorized to participate in a pharmacy's technician training program.

(25) Texas Controlled Substances Act--The Texas Controlled Substances Act, Health and Safety Code, Chapter 481, as amended.

(c) Personnel.

(1) Pharmacist-in-charge.

(A) General. Each ambulatory surgical center shall have one pharmacist-in-charge who is employed or under contract, at least on a consulting or part-time basis, but may be employed on a full-time basis.

(B) Responsibilities. The pharmacist-in-charge shall have the responsibility for, at a minimum, the following:

(i) establishing specifications for procurement and storage of all materials, including drugs, chemicals, and biologicals;

(ii) participating in the development of a formulary for the ASC, subject to approval of the appropriate committee of the ASC;

(iii) distributing drugs to be administered to patients pursuant to the practitioner's medication order;

(iv) filling and labeling all containers from which drugs are to be distributed or dispensed;

(v) maintaining and making available a sufficient inventory of antidotes and other emergency drugs, both in the pharmacy and patient care areas, as well as current antidote information, telephone numbers of regional poison control center and other emergency assistance organizations, and such other materials and information as may be deemed necessary by the appropriate committee of the ASC;

(vi) maintaining records of all transactions of the ASC pharmacy as may be required by applicable state and federal law, and as may be necessary to maintain accurate control over and accountability for all pharmaceutical materials;

(vii) participating in those aspects of the ASC's patient care evaluation program which relate to pharmaceutical material utilization and effectiveness;

(viii) participating in teaching and/or research programs in the ASC;

(ix) implementing the policies and decisions of the appropriate committee(s) relating to pharmaceutical services of the ASC;

(x) providing effective and efficient messenger and delivery service to connect the ASC pharmacy with appropriate areas of the ASC on a regular basis throughout the normal workday of the ASC;

(xi) labeling, storing, and distributing investigational new drugs, including maintaining information in the pharmacy and nursing station where such drugs are being administered, concerning the dosage form, route of administration, strength, actions, uses, side effects, adverse effects, interactions, and symptoms of toxicity of investigational new drugs;

(xii) meeting all inspection and other requirements of the Texas Pharmacy Act and this subsection;

(xiii) maintaining records in a data processing system such that the data processing system is in compliance with the requirements for a Class C (institutional) pharmacy located in a free-standing ASC; and

(xiv) ensuring that a pharmacist visits the ASC at least once each calendar week that the facility is open.

(2) Consultant pharmacist.

(A) The consultant pharmacist may be the pharmacist-in-charge.

(B) A written contract shall exist between the ASC and any consultant pharmacist, and a copy of the written contract shall be made available to the board upon request.

(3) Pharmacists.

(A) General.

(i) The pharmacist-in-charge shall be assisted by a sufficient number of additional licensed pharmacists as may be required to operate the ASC pharmacy competently, safely, and adequately to meet the needs of the patients of the facility.

(ii) All pharmacists shall assist the pharmacist-in-charge in meeting the responsibilities as outlined in paragraph (1)(B) of this subsection and in ordering, administering, and accounting for pharmaceutical materials.

(iii) All pharmacists shall be responsible for any delegated act performed by pharmacy technicians or pharmacy technician trainees under his or her supervision.

(iv) All pharmacists while on duty shall be responsible for complying with all state and federal laws or rules governing the practice of pharmacy.

(B) Duties. Duties of the pharmacist-in-charge and all other pharmacists shall include, but need not be limited to, the following:

(i) receiving and interpreting prescription drug orders and oral medication orders and reducing these orders to writing either manually or electronically;

(ii) selecting prescription drugs and/or devices and/or suppliers; and

(iii) interpreting patient profiles.

(C) Special requirements for compounding non-sterile preparations. All pharmacists engaged in compounding non-sterile preparations shall meet the training requirements specified in §291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations).

(4) Pharmacy technicians and pharmacy technician trainees.

(A) General. All pharmacy technicians and pharmacy technician trainees shall meet the training requirements specified in §297.6 of this title (relating to Pharmacy Technician and Pharmacy Technician Trainee Training).

(B) Duties. Pharmacy technicians and pharmacy technician trainees may not perform any of the duties listed in paragraph (3)(B) of this subsection. Duties may include, but need not be limited to, the following functions, under the direct supervision of a pharmacist:

(i) prepacking and labeling unit and multiple dose packages, provided a pharmacist supervises and conducts a final check and affixes his or her name, initials, or electronic signature to the appropriate quality control records prior to distribution;

(ii) preparing, packaging, compounding, or labeling prescription drugs pursuant to medication orders, provided a pharmacist supervises and checks the preparation;

(iii) compounding non-sterile preparations pursuant to medication orders provided the pharmacy technicians or pharmacy technician trainees have completed the training specified in §291.131 of this title;

(iv) bulk compounding, provided a pharmacist supervises and conducts in-process and final checks and affixes his or her name, initials, or electronic signature to the appropriate quality control records prior to distribution;

(v) distributing routine orders for stock supplies to patient care areas;

(vi) entering medication order and drug distribution information into a data processing system, provided judgmental decisions are not required and a pharmacist checks the accuracy of the information entered into the system prior to releasing the order or in compliance with the absence of pharmacist requirements contained in subsection (d)(6)(D) and (E) of this section;

(vii) maintaining inventories of drug supplies;

(viii) maintaining pharmacy records; and

(ix) loading drugs into an automated medication supply system. For the purpose of this clause, direct supervision may be accomplished by physically present supervision or electronic monitoring by a pharmacist.

(C) Procedures.

(i) Pharmacy technicians and pharmacy technician trainees shall handle medication orders in accordance with standard written procedures and guidelines.

(ii) Pharmacy technicians and pharmacy technician trainees shall handle prescription drug orders in the same manner as pharmacy technicians or pharmacy technician trainees working in a Class A pharmacy.

(D) Special requirements for compounding non-sterile preparations. All pharmacy technicians and pharmacy technician trainees engaged in compounding non-sterile preparations shall meet the training requirements specified in §291.131 of this title.

(5) Owner. The owner of an ASC pharmacy shall have responsibility for all administrative and operational functions of the pharmacy. The pharmacist-in-charge may advise the owner on administrative and operational concerns. The owner shall have responsibility for, at a minimum, the following, and if the owner is not a Texas licensed pharmacist, the owner shall consult with the pharmacist-in-charge or another Texas licensed pharmacist:

(A) establishing policies for procurement of prescription drugs and devices and other products dispensed from the ASC pharmacy;

(B) establishing and maintaining effective controls against the theft or diversion of prescription drugs;

(C) if the pharmacy uses an automated medication supply system, reviewing and approving all policies and procedures for system operation, safety, security, accuracy and access, patient confidentiality, prevention of unauthorized access, and malfunction;

(D) providing the pharmacy with the necessary equipment and resources commensurate with its level and type of practice; and

(E) establishing policies and procedures regarding maintenance, storage, and retrieval of records in a data processing system such that the system is in compliance with state and federal requirements.

(6) Identification of pharmacy personnel. All pharmacy personnel shall be identified as follows:

(A) Pharmacy technicians. All pharmacy technicians shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacy technician.

(B) Pharmacy technician trainees. All pharmacy technician trainees shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacy technician trainee.

(C) Pharmacist interns. All pharmacist interns shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacist intern.

(D) Pharmacists. All pharmacists shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacist.

(d) Operational standards.

(1) Licensing requirements.

(A) An ASC pharmacy shall register annually or biennially with the board on a pharmacy license application provided by the board, following the procedures specified in §291.1 of this title (relating to Pharmacy License Application).

(B) An ASC pharmacy which changes ownership shall notify the board within 10 days of the change of ownership and apply for a new and separate license as specified in §291.3 of this title (relating to Required Notifications).

(C) An ASC pharmacy which changes location and/or name shall notify the board of the change within 10 days and file for an amended license as specified in §291.3 of this title.

(D) An ASC pharmacy owned by a partnership or corporation which changes managing officers shall notify the board in writing of the names of the new managing officers within 10 days of the change, following the procedures in §291.3 of this title.

(E) An ASC pharmacy shall notify the board in writing within 10 days of closing, following the procedures in §291.5 of this title (relating to Closing a Pharmacy).

(F) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged for issuance and renewal of a license and the issuance of an amended license.

(G) A separate license is required for each principal place of business and only one pharmacy license may be issued to a specific location.

(H) An ASC pharmacy, licensed under the Act, §560.051(a)(3), concerning institutional pharmacy (Class C), which also operates another type of pharmacy which would otherwise be required to be licensed under the Act, §560.051(a)(1), concerning community pharmacy (Class A), or the Act, §560.051(a)(2), concerning nuclear pharmacy (Class B), is not required to secure a license for the other type of pharmacy; provided, however, such license is required to comply with the provisions of §291.31 of this title (relating to Definitions), §291.32 of this title (relating to Personnel), §291.33 of this title (relating to Operational Standards), §291.34 of this title (relating to Records), and §291.35 of this title (relating to Official Prescription Requirements), or §291.51 of this title (relating to Purpose), §291.52 of this title (relating to Definitions), §291.53 of this title (relating to Personnel), §291.54 of this title (relating to Operational Standards), and §291.55 of this title (relating to Records), contained in Nuclear Pharmacy (Class B), to the extent such sections are applicable to the operation of the pharmacy.

(I) An ASC pharmacy engaged in the compounding of non-sterile preparations shall comply with the provisions of §291.131 of this title.

(J) ASC pharmacy personnel shall not compound sterile preparations unless the pharmacy has applied for and obtained a Class C-S pharmacy license.

(K) An ASC pharmacy engaged in the provision of remote pharmacy services, including storage and dispensing of prescription drugs, shall comply with the provisions of §291.121 of this title (relating to Remote Pharmacy Services).

(L) An ASC pharmacy engaged in centralized prescription dispensing and/or prescription drug or medication order processing shall comply with the provisions of §291.123 of this title (relating to Central Prescription Drug or Medication Order Processing) and/or §291.125 of this title (relating to Centralized Prescription Dispensing).

(2) Environment.

(A) General requirements.

(i) Each ambulatory surgical center shall have a designated work area separate from patient areas, and which shall have space adequate for the size and scope of pharmaceutical services and shall have adequate space and security for the storage of drugs.

(ii) The ASC pharmacy shall be arranged in an orderly fashion and shall be kept clean. All required equipment shall be clean and in good operating condition.

(B) Special requirements.

(i) The ASC pharmacy shall have locked storage for Schedule II controlled substances and other controlled drugs requiring additional security.

(ii) The ASC pharmacy shall have a designated area for the storage of poisons and externals separate from drug storage areas.

(C) Security.

(i) The pharmacy and storage areas for prescription drugs and/or devices shall be enclosed and capable of being locked by key, combination, or other mechanical or electronic means, so as to prohibit access by unauthorized individuals. Only individuals authorized by the pharmacist-in-charge may enter the pharmacy or have access to storage areas for prescription drugs and/or devices.

(ii) The pharmacist-in-charge shall consult with ASC personnel with respect to security of the drug storage areas, including provisions for adequate safeguards against theft or diversion of dangerous drugs and controlled substances, and to security of records for such drugs.

(iii) The pharmacy shall have locked storage for Schedule II controlled substances and other drugs requiring additional security.

(3) Equipment and supplies. Ambulatory surgical centers supplying drugs for postoperative use shall have the following equipment and supplies:

(A) data processing system including a printer or comparable equipment;

(B) adequate supply of child-resistant, moisture-proof, and light-proof containers; and

(C) adequate supply of prescription labels and other applicable identification labels.

(4) Library. A reference library shall be maintained that includes the following in hard copy or electronic format and that pharmacy personnel shall be capable of accessing at all times:

(A) current copies of the following:

(i) Texas Pharmacy Act and rules;

(ii) Texas Dangerous Drug Act and rules;

(iii) Texas Controlled Substances Act and rules;

(iv) Federal Controlled Substances Act and rules or official publication describing the requirements of the Federal Controlled Substances Act and rules;

(B) at least one current or updated general drug information reference which is required to contain drug interaction information including information needed to determine severity or significance of the interaction and appropriate recommendations or actions to be taken; and

(C) basic antidote information and the telephone number of the nearest regional poison control center.

(5) Drugs.

(A) Procurement, preparation, and storage.

(i) The pharmacist-in-charge shall have the responsibility for the procurement and storage of drugs, but may receive input from other appropriate staff of the facility, relative to such responsibility.

(ii) The pharmacist-in-charge shall have the responsibility for determining specifications of all drugs procured by the facility.

(iii) ASC pharmacies may not sell, purchase, trade, or possess prescription drug samples, unless the pharmacy meets the requirements as specified in §291.16 of this title (relating to Samples).

(iv) All drugs shall be stored at the proper temperatures, as defined in the USP/NF and in §291.15 of this title (relating to Storage of Drugs).

(v) Any drug bearing an expiration date may not be dispensed or distributed beyond the expiration date of the drug.

(vi) Outdated drugs shall be removed from dispensing stock and shall be quarantined together until such drugs are disposed of.

(B) Formulary.

(i) A formulary may be developed by an appropriate committee of the ASC.

(ii) The pharmacist-in-charge or consultant pharmacist shall be a full voting member of any committee which involves pharmaceutical services.

(iii) A practitioner may grant approval for pharmacists at the ASC to interchange, in accordance with the facility's formulary, for the drugs on the practitioner's medication orders provided:

(I) a formulary has been developed;

(II) the formulary has been approved by the medical staff of the ASC;

(III) there is a reasonable method for the practitioner to override any interchange; and

(IV) the practitioner authorizes a pharmacist in the ASC to interchange on his/her medication orders in accordance with

the facility's formulary through his/her written agreement to abide by the policies and procedures of the medical staff and facility.

(C) Prepackaging and loading drugs into automated medication supply system.

(i) Prepackaging of drugs.

(I) Drugs may be prepackaged in quantities suitable for distribution to other Class C pharmacies under common ownership or for internal distribution only by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist.

(II) The label of a prepackaged unit shall indicate:

(-a-) brand name and strength of the drug; or if no brand name, then the generic name, strength, and name of the manufacturer or distributor;

(-b-) facility's lot number;

(-c-) expiration date;

(-d-) quantity of the drug, if quantity is greater than one; and

(-e-) if the drug is distributed to another Class C pharmacy, name of the facility responsible for prepackaging the drug.

(III) Records of prepackaging shall be maintained to show:

(-a-) the name of the drug, strength, and dosage form;

(-b-) facility's lot number;

(-c-) manufacturer or distributor;

(-d-) manufacturer's lot number;

(-e-) expiration date;

(-f-) quantity per prepackaged unit;

(-g-) number of prepackaged units;

(-h-) date packaged;

(-i-) name, initials, or electronic signature of the preparer;

(-j-) signature or electronic signature of the responsible pharmacist; and

(-k-) if the drug is distributed to another Class C pharmacy, name of the facility receiving the prepackaged drug.

(IV) Stock packages, repackaged units, and control records shall be quarantined together until checked/released by the pharmacist.

(ii) Loading bulk unit of use drugs into automated medication supply systems. Automated medication supply systems may be loaded with bulk unit of use drugs only by a pharmacist, by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist, or by a licensed nurse who is authorized by the pharmacist to perform the loading of the automated medication supply system. For the purpose of this clause, direct supervision may be accomplished by physically present supervision or electronic monitoring by a pharmacist. In order for the pharmacist to electronically monitor, the medication supply system must allow for bar code scanning to verify the loading of drugs, and a record of the loading must be maintained by the system and accessible for electronic review by the pharmacist.

(6) Medication orders.

(A) Drugs may be administered to patients in ASCs only on the order of a practitioner. No change in the order for drugs may be made without the approval of a practitioner except as authorized by the practitioner in compliance with paragraph (5)(B) of this subsection.

(B) Drugs may be distributed only pursuant to the practitioner's medication order.

(C) ASC pharmacies shall be exempt from the labeling provisions and patient notification requirements of §562.006 and §562.009 of the Act, as respects drugs distributed pursuant to medication orders.

(D) In ASCs with a full-time pharmacist, if a practitioner orders a drug for administration to a bona fide patient of the facility when the pharmacy is closed, the following is applicable:

(i) prescription drugs and devices only in sufficient quantities for immediate therapeutic needs of a patient may be removed from the ASC pharmacy;

(ii) only a designated licensed nurse or practitioner may remove such drugs and devices;

(iii) a record shall be made at the time of withdrawal by the authorized person removing the drugs and devices. The record shall contain the following information:

(I) name of the patient;

(II) name of device or drug, strength, and dosage form;

(III) dose prescribed;

(IV) quantity withdrawn;

(V) time and date; and

(VI) signature or electronic signature of the person making the withdrawal;

(iv) the medication order in the patient's chart may substitute for such record, provided the medication order meets all the requirements of clause (iii) of this subparagraph;

(v) the pharmacist shall verify the withdrawal of a controlled substance as soon as practical, but in no event more than 72 hours from the time of such withdrawal; and

(vi) the pharmacist shall verify the withdrawal of a dangerous drug at a reasonable interval, but such verification must occur at least once in every calendar week.

(E) In ASCs with a part-time or consultant pharmacist, if a practitioner orders a drug for administration to a bona fide patient of the ASC when the pharmacist is not on duty, or when the pharmacy is closed, the following is applicable:

(i) prescription drugs and devices only in sufficient quantities for therapeutic needs may be removed from the ASC pharmacy;

(ii) only a designated licensed nurse or practitioner may remove such drugs and devices;

(iii) a record shall be made at the time of withdrawal by the authorized person removing the drug or device as described in subparagraph (D)(iii) and (iv) of this subsection; and

(iv) the pharmacist shall verify withdrawals at a reasonable interval, but such verification must occur at least once in every calendar week that the pharmacy is open.

(7) Floor stock. In facilities using a floor stock method of drug distribution, the pharmacy shall establish designated floor stock areas outside of the central pharmacy where drugs may be stored, in accordance with the pharmacy's policies and procedures. The following

is applicable for removing drugs or devices in the absence of a pharmacist:

(A) prescription drugs and devices may be removed from the pharmacy only in the original manufacturer's container or prepackaged container;

(B) only a designated licensed nurse or practitioner may remove such drugs and devices;

(C) a record shall be made at the time of withdrawal by the authorized person removing the drug or device and the record shall contain the following information:

(i) name of the drug, strength, and dosage form;

(ii) quantity removed;

(iii) location of floor stock;

(iv) date and time; and

(v) signature or electronic signature of person making the withdrawal;

(D) the medication order in the patient's chart may substitute for the record required in subparagraph (C) of this paragraph, provided the medication order meets all the requirements of subparagraph (C) of this paragraph; and

(E) if a stored drug or device is returned to the pharmacy from floor stock areas, a record shall be made by the authorized person returning the drug or device. The record shall contain the following information:

(i) drug name, strength, and dosage form, or device name;

(ii) quantity returned;

(iii) previous floor stock location for the drug or device;

(iv) date and time; and

(v) signature or electronic signature of person returning the drug or device.

(8) Policies and procedures. Written policies and procedures for a drug distribution system, appropriate for the ambulatory surgical center, shall be developed and implemented by the pharmacist-in-charge with the advice of the appropriate committee. The written policies and procedures for the drug distribution system shall include, but not be limited to, procedures regarding the following:

(A) controlled substances;

(B) investigational drugs;

(C) prepackaging and manufacturing;

(D) medication errors;

(E) orders of physician or other practitioner;

(F) floor stocks;

(G) adverse drug reactions;

(H) drugs brought into the facility by the patient;

(I) self-administration;

(J) emergency drug tray;

(K) formulary, if applicable;

(L) drug storage areas;

(M) drug samples;

(N) drug product defect reports;

(O) drug recalls;

(P) outdated drugs;

(Q) preparation and distribution of IV admixtures;

(R) procedures for supplying drugs for postoperative use, if applicable;

(S) use of automated medication supply systems;

(T) use of data processing systems; and

(U) drug regimen review.

(9) Drugs supplied for postoperative use. Drugs supplied to patients for postoperative use shall be supplied according to the following procedures.

(A) Drugs may only be supplied to patients who have been admitted to the ASC.

(B) Drugs may only be supplied in accordance with the system of control and accountability established for drugs supplied from the ambulatory surgical center; such system shall be developed and supervised by the pharmacist-in-charge or staff pharmacist designated by the pharmacist-in-charge.

(C) Only drugs listed on the approved postoperative drug list may be supplied; such list shall be developed by the pharmacist-in-charge and the medical staff and shall consist of drugs of the nature and type to meet the immediate postoperative needs of the ambulatory surgical center patient.

(D) Drugs may only be supplied in prepackaged quantities not to exceed a 72-hour supply in suitable containers and appropriately prelabeled (including name, address, and phone number of the facility, and necessary auxiliary labels) by the pharmacy provided, however, that topicals and ophthalmics in original manufacturer's containers may be supplied in a quantity exceeding a 72-hour supply.

(E) At the time of delivery of the drug, the practitioner shall complete the label, such that the prescription container bears a label with at least the following information:

(i) date supplied;

(ii) name of practitioner;

(iii) name of patient;

(iv) directions for use;

(v) brand name and strength of the drug; or if no brand name, then the generic name of the drug dispensed, strength, and the name of the manufacturer or distributor of the drug; and

(vi) unique identification number.

(F) After the drug has been labeled, the practitioner or a licensed nurse under the supervision of the practitioner shall give the appropriately labeled, prepackaged medication to the patient.

(G) A perpetual record of drugs which are supplied from the ASC shall be maintained which includes:

(i) name, address, and phone number of the facility;

(ii) date supplied;

(iii) name of practitioner;

(iv) name of patient;

(v) directions for use;

(vi) brand name and strength of the drug; or if no brand name, then the generic name of the drug dispensed, strength, and the name of the manufacturer or distributor of the drug; and

(vii) unique identification number.

(H) The pharmacist-in-charge, or a pharmacist designated by the pharmacist-in-charge, shall review the records at least once in every calendar week that the pharmacy is open.

(10) Drug regimen review.

(A) A pharmacist shall evaluate medication orders and patient medication records for:

(i) known allergies;

(ii) rational therapy--contraindications;

(iii) reasonable dose and route of administration;

(iv) reasonable directions for use;

(v) duplication of therapy;

(vi) drug-drug interactions;

(vii) drug-food interactions;

(viii) drug-disease interactions;

(ix) adverse drug reactions;

(x) proper utilization, including overutilization or underutilization; and

(xi) clinical laboratory or clinical monitoring methods to monitor and evaluate drug effectiveness, side effects, toxicity, or adverse effects, and appropriateness to continued use of the drug in its current regimen.

(B) A retrospective, random drug regimen review as specified in the pharmacy's policies and procedures shall be conducted on a periodic basis to verify proper usage of drugs not to exceed 31 days between such reviews.

(C) Any questions regarding the order must be resolved with the prescriber and a written notation of these discussions made and maintained.

(e) Records.

(1) Maintenance of records.

(A) Every inventory or other record required to be kept under the provisions of this section (relating to Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center) shall be:

(i) kept by the pharmacy and be available, for at least two years from the date of such inventory or record, for inspecting and copying by the board or its representative, and other authorized local, state, or federal law enforcement agencies; and

(ii) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the board. If the pharmacy maintains the records in an electronic format, the requested records must be provided in a mutually agreeable electronic format if specifically requested by the board or its representative. Failure to provide the records set out in this subsection, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.

(B) Records of controlled substances listed in Schedule II shall be maintained separately and readily retrievable from all other records of the pharmacy.

(C) Records of controlled substances listed in Schedules III - V shall be maintained separately or readily retrievable from all other records of the pharmacy. For purposes of this subparagraph, "readily retrievable" means that the controlled substances shall be asterisked, redlined, or in some other manner readily identifiable apart from all other items appearing on the record.

(D) Records, except when specifically required to be maintained in original or hard copy form, may be maintained in an alternative data retention system, such as a data processing or direct imaging system provided:

(i) the records in the alternative data retention system contain all of the information required on the manual record; and

(ii) the alternative data retention system is capable of producing a hard copy of the record upon the request of the board, its representative, or other authorized local, state, or federal law enforcement or regulatory agencies.

(E) Controlled substance records shall be maintained in a manner to establish receipt and distribution of all controlled substances.

(F) An ASC pharmacy shall maintain a perpetual inventory of controlled substances listed in Schedules II - V which shall be verified for completeness and reconciled at least once in every calendar week that the pharmacy is open.

(G) Distribution records for controlled substances, listed in Schedules II - V, shall include the following information:

(i) patient's name;

(ii) practitioner's name who ordered the drug;

(iii) name of drug, dosage form, and strength;

(iv) time and date of administration to patient and quantity administered;

(v) signature or electronic signature of individual administering the controlled substance;

(vi) returns to the pharmacy; and

(vii) waste (waste is required to be witnessed and cosigned, manually or electronically, by another individual).

(H) The record required by subparagraph (G) of this paragraph shall be maintained separately from patient records.

(I) A pharmacist shall conduct an audit by randomly comparing the distribution records required by subparagraph (G) with the medication orders in the patient record on a periodic basis to verify proper administration of drugs not to exceed 30 days between such reviews.

(2) Patient records.

(A) Each medication order or set of orders issued together shall bear the following information:

(i) patient name;

(ii) drug name, strength, and dosage form;

(iii) directions for use;

(iv) date; and

(v) signature or electronic signature of the practitioner or that of his or her authorized agent, defined as an employee or consultant/full or part-time pharmacist of the ASC.

(B) Medication orders shall be maintained with the medication administration record in the medical records of the patient.

(3) General requirements for records maintained in a data processing system.

(A) If an ASC pharmacy's data processing system is not in compliance with the board's requirements, the pharmacy must maintain a manual recordkeeping system.

(B) The facility shall maintain a backup copy of information stored in the data processing system using disk, tape, or other electronic backup system and update this backup copy on a regular basis to assure that data is not lost due to system failure.

(C) A pharmacy that changes or discontinues use of a data processing system must:

(i) transfer the records to the new data processing system; or

(ii) purge the records to a printout which contains:

(I) all of the information required on the original document; or

(II) for records of distribution and return for all controlled substances, the same information as required on the audit trail printout as specified in subparagraph (F) of this paragraph. The information on the printout shall be sorted and printed by drug name and list all distributions and returns chronologically.

(D) Information purged from a data processing system must be maintained by the pharmacy for two years from the date of initial entry into the data processing system.

(E) The pharmacist-in-charge shall report to the board in writing any significant loss of information from the data processing system within 10 days of discovery of the loss.

(F) The data processing system shall have the capacity to produce a hard copy printout of an audit trail of drug distribution and return for any strength and dosage form of a drug (by either brand or generic name or both) during a specified time period. This printout shall contain the following information:

(i) patient's name and room number or patient's facility identification number;

(ii) prescribing or attending practitioner's name;

(iii) name, strength, and dosage form of the drug product actually distributed;

(iv) total quantity distributed from and returned to the pharmacy;

(v) if not immediately retrievable via electronic image, the following shall also be included on the printout:

(I) prescribing or attending practitioner's address; and

(II) practitioner's DEA registration number, if the medication order is for a controlled substance.

(G) An audit trail printout for each strength and dosage form of the drugs distributed during the preceding month shall be produced at least monthly and shall be maintained in a separate file at the

facility. The information on this printout shall be sorted by drug name and list all distributions/returns for that drug chronologically.

(H) The pharmacy may elect not to produce the monthly audit trail printout if the data processing system has a workable (electronic) data retention system which can produce an audit trail of drug distribution and returns for the preceding two years. The audit trail required in this clause shall be supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy, or other authorized local, state, or federal law enforcement or regulatory agencies.

(I) In the event that an ASC pharmacy which uses a data processing system experiences system downtime, the pharmacy must have an auxiliary procedure which will ensure that all data is retained for online data entry as soon as the system is available for use again.

(4) Distribution of controlled substances to another registrant. A pharmacy may distribute controlled substances to a practitioner, another pharmacy, or other registrant, without being registered to distribute, under the following conditions.

(A) The registrant to whom the controlled substance is to be distributed is registered under the Controlled Substances Act to possess that controlled substance.

(B) The total number of dosage units of controlled substances distributed by a pharmacy may not exceed 5.0% of all controlled substances dispensed by the pharmacy during the 12-month period in which the pharmacy is registered; if at any time it does exceed 5.0%, the pharmacy is required to obtain an additional registration to distribute controlled substances.

(C) If the distribution is for a Schedule III, IV, or V controlled substance, a record shall be maintained which indicates:

(i) the actual date of distribution;

(ii) the name, strength, and quantity of controlled substances distributed;

(iii) the name, address, and DEA registration number of the distributing pharmacy; and

(iv) the name, address, and DEA registration number of the pharmacy, practitioner, or other registrant to whom the controlled substances are distributed.

(D) A pharmacy shall comply with 21 CFR 1305 regarding the DEA order form (DEA 222) requirements when distributing a Schedule II controlled substance.

(5) Other records. Other records to be maintained by the pharmacy include:

(A) a log of the initials or identification codes which identifies each pharmacist by name. The initials or identification code shall be unique to ensure that each pharmacist can be identified, i.e., identical initials or identification codes cannot be used. Such log shall be maintained at the pharmacy for at least seven years from the date of the transaction;

(B) suppliers' invoices of dangerous drugs and controlled substances dated and initialed or signed by the person receiving the drugs;

(i) a pharmacist shall verify that the controlled substances listed on the invoices were added to the pharmacy's perpetual inventory by clearly recording his/her initials and the date of review of the perpetual inventory; and

(ii) for controlled substances, the documents retained must contain the name, strength, and quantity of controlled substances distributed, and the name, address, and DEA number of both the supplier and the receiving pharmacy;

(C) supplier's credit memos for controlled substances and dangerous drugs;

(D) a copy of inventories required by §291.17 of this title (relating to Inventory Requirements) except that a perpetual inventory of controlled substances listed in Schedule II may be kept in a data processing system if the data processing system is capable of producing a copy of the perpetual inventory on-site;

(E) reports of surrender or destruction of controlled substances and/or dangerous drugs to an appropriate state or federal agency or reverse distributor;

(F) records of distribution of controlled substances and/or dangerous drugs to other pharmacies, practitioners, or registrants; and

(G) a copy of any notification required by the Texas Pharmacy Act or these rules, including, but not limited to, the following:

(i) reports of theft or significant loss of controlled substances to DEA and the board;

(ii) notification of a change in pharmacist-in-charge of a pharmacy; and

(iii) reports of a fire or other disaster which may affect the strength, purity, or labeling of drugs, medications, devices, or other materials used in the diagnosis or treatment of injury, illness, and disease.

(6) Permission to maintain central records. Any pharmacy that uses a centralized recordkeeping system for invoices and financial data shall comply with the following procedures.

(A) Controlled substance records. Invoices and financial data for controlled substances may be maintained at a central location provided the following conditions are met:

(i) Prior to the initiation of central recordkeeping, the pharmacy submits written notification by registered or certified mail to the divisional director of DEA as required by the Code of Federal Regulations, Title 21, §1304(a), and submits a copy of this written notification to the board. Unless the registrant is informed by the divisional director of DEA that permission to keep central records is denied, the pharmacy may maintain central records commencing 14 days after receipt of notification by the divisional director;

(ii) The pharmacy maintains a copy of the notification required in this subparagraph; and

(iii) The records to be maintained at the central record location shall not include executed DEA order forms, prescription drug orders, or controlled substance inventories, which shall be maintained at the pharmacy.

(B) Dangerous drug records. Invoices and financial data for dangerous drugs may be maintained at a central location.

(C) Access to records. If the records are kept in any form requiring special equipment to render the records easily readable, the pharmacy shall provide access to such equipment with the records.

(D) Delivery of records. The pharmacy agrees to deliver all or any part of such records to the pharmacy location within

two business days of written request of a board agent or any other authorized official.

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

Filed with the Office of the Secretary of State on August 20, 2021.

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Allison Vordenbaumen Benz, R.Ph., M.S.

Executive Director

Texas State Board of Pharmacy

Effective date: September 9, 2021

Proposal publication date: June 25, 2021

For further information, please call: (512) 305-8010



SUBCHAPTER G. SERVICES PROVIDED BY PHARMACIES

22 TAC §291.121

The Texas State Board of Pharmacy adopts amendments to §291.121, concerning Remote Pharmacy Services. These amendments are adopted without changes to the proposed text as published in the June 25, 2021, issue of the *Texas Register* (46 TexReg 3823). The amended rule will not be republished.

The amendments authorize a Class A or Class C pharmacy to provide remote pharmacy services using an automated dispensing and delivery system and correct grammatical errors.

No comments were received.

The amendments are adopted under §§551.002 and 554.051 of the Texas Pharmacy Act (Chapters 551 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by this adoption: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

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

Filed with the Office of the Secretary of State on August 20, 2021.

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SUBCHAPTER H. OTHER CLASSES OF PHARMACY

22 TAC §291.151

The Texas State Board of Pharmacy adopts amendments to §291.151, concerning Pharmacies Located in a Freestanding Emergency Medical Care Facility (Class F). These amendments are adopted with changes to the proposed text as published in the June 25, 2021, issue of the *Texas Register* at (46 TexReg 3835). The rule will be republished.

The amendments allow a licensed nurse who is authorized by the pharmacist to perform the loading of an automated medication supply system; update the time interval in which a pharmacist must verify a drug withdrawal; update the requirements for using a floor stock method of drug distribution; update records requirements; update references to DEA 222 form requirements to be consistent with federal regulations; and correct grammatical errors.

The Board received a comment from Lisa Walker, R.Ph., in support of the amendment to remove the language allowing a medication order in a patient's chart to substitute for the record of withdrawal of a drug or device in the absence of a pharmacist to restock a floor stock area, expressing concern about the amendment to require an FEMCF pharmacy with a part-time or consultant pharmacy to make a record of withdrawal of a drug or device from the pharmacy in the absence of a pharmacist for administration to a patient, and suggested limiting the rule to only require a record of withdrawal for controlled substances removed from the pharmacy pursuant to a medication order. The Board declines to make this change.

The Board received a comment jointly submitted by Christopher M. Dembny, Joseph Staller, Jeff Neale, Beto Quezada, Libby Gibbs, Lisa Walker, Julie Sifford, and Jerry Jackson, R.Phs., in support of the amendment to allow a licensed nurse authorized by a pharmacist to perform the loading of an automated medication supply system and expressing concern about the amendment to require an FEMCF pharmacy with a part-time or consultant pharmacy to make a record of withdrawal of a drug or device from the pharmacy in the absence of a pharmacist for administration to a patient.

The Board received a comment from the Texas Ambulatory Surgery Center Society in support of the amendment to allow a licensed nurse authorized by a pharmacist to perform the loading of an automated medication supply system and expressing concern about the amendment to remove the language allowing a medication order in a patient's chart to substitute for the record of withdrawal of a drug or device in the absence of a pharmacist to restock a floor stock area. The Board agreed and did not remove the language allowing a medication order in a patient's chart to substitute for the record of withdrawal of a drug or device in the absence of a pharmacist to restock a floor stock area.

The amendments are adopted under §§551.002 and 554.051 of the Texas Pharmacy Act (Chapters 551 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by this adoption: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

§291.151. *Pharmacies Located in a Freestanding Emergency Medical Care Facility (Class F).*

(a) Purpose. The purpose of this section is to provide standards in the conduct, practice activities, and operation of a pharmacy located

in a freestanding emergency medical care facility that is licensed by the Texas Department of State Health Services or in a freestanding emergency medical care facility operated by a hospital that is exempt from registration as provided by §254.052, Health and Safety Code. Class F pharmacies located in a freestanding emergency medical care facility shall comply with this section.

(b) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Act--The Texas Pharmacy Act, Occupations Code, Subtitle J, as amended.

(2) Administer--The direct application of a prescription drug by injection, inhalation, ingestion, or any other means to the body of a patient by:

(A) a practitioner, an authorized agent under his supervision, or other person authorized by law; or

(B) the patient at the direction of a practitioner.

(3) Automated medication supply system--A mechanical system that performs operations or activities relative to the storage and distribution of medications for administration and which collects, controls, and maintains all transaction information.

(4) Board--The Texas State Board of Pharmacy.

(5) Consultant pharmacist--A pharmacist retained by a facility on a routine basis to consult with the FEMCF in areas that pertain to the practice of pharmacy.

(6) Controlled substance--A drug, immediate precursor, or other substance listed in Schedules I - V or Penalty Groups 1 - 4 of the Texas Controlled Substances Act, as amended, or a drug immediate precursor, or other substance included in Schedules I - V of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended (Public Law 91-513).

(7) Dispense--Preparing, packaging, compounding, or labeling for delivery a prescription drug or device in the course of professional practice to an ultimate user or his agent by or pursuant to the lawful order of a practitioner.

(8) Distribute--The delivery of a prescription drug or device other than by administering or dispensing.

(9) Downtime--Period of time during which a data processing system is not operable.

(10) Electronic signature--A unique security code or other identifier which specifically identifies the person entering information into a data processing system. A facility which utilizes electronic signatures must:

(A) maintain a permanent list of the unique security codes assigned to persons authorized to use the data processing system; and

(B) have an ongoing security program which is capable of identifying misuse and/or unauthorized use of electronic signatures.

(11) Floor stock--Prescription drugs or devices not labeled for a specific patient and maintained at a nursing station or other FEMCF department (excluding the pharmacy) for the purpose of administration to a patient of the FEMCF.

(12) Formulary--List of drugs approved for use in the FEMCF by an appropriate committee of the FEMCF.

(13) Freestanding emergency medical care facility (FEMCF)--A freestanding facility that is licensed by the Texas Department of State Health Services pursuant to Chapter 254, Health and Safety Code, to provide emergency care to patients.

(14) Hard copy--A physical document that is readable without the use of a special device (i.e., data processing system, computer, etc.).

(15) Investigational new drug--New drug intended for investigational use by experts qualified to evaluate the safety and effectiveness of the drug as authorized by the federal Food and Drug Administration.

(16) Medication order--An order from a practitioner or his authorized agent for administration of a drug or device.

(17) Pharmacist-in-charge--Pharmacist designated on a pharmacy license as the pharmacist who has the authority or responsibility for a pharmacy's compliance with laws and rules pertaining to the practice of pharmacy.

(18) Pharmacy--Area or areas in a facility, separate from patient care areas, where drugs are stored, bulk compounded, delivered, compounded, dispensed, and/or distributed to other areas or departments of the FEMCF, or dispensed to an ultimate user or his or her agent.

(19) Prescription drug--

(A) A substance for which federal or state law requires a prescription before it may be legally dispensed to the public;

(B) A drug or device that under federal law is required, prior to being dispensed or delivered, to be labeled with either of the following statements:

(i) Caution: federal law prohibits dispensing without prescription or "Rx only" or another legend that complies with federal law; or

(ii) Caution: federal law restricts this drug to use by or on order of a licensed veterinarian; or

(C) A drug or device that is required by any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by a practitioner only.

(20) Prescription drug order--

(A) An order from a practitioner or his authorized agent to a pharmacist for a drug or device to be dispensed; or

(B) An order pursuant to Subtitle B, Chapter 157, Occupations Code.

(21) Full-time pharmacist--A pharmacist who works in a pharmacy from 30 to 40 hours per week or if the pharmacy is open less than 60 hours per week, one-half of the time the pharmacy is open.

(22) Part-time pharmacist--A pharmacist who works less than full-time.

(23) Pharmacy technician--An individual who is registered with the board as a pharmacy technician and whose responsibility in a pharmacy is to provide technical services that do not require professional judgment regarding preparing and distributing drugs and who works under the direct supervision of and is responsible to a pharmacist.

(24) Pharmacy technician trainee--An individual who is registered with the board as a pharmacy technician trainee and is authorized to participate in a pharmacy's technician training program.

(25) Texas Controlled Substances Act--The Texas Controlled Substances Act, Health and Safety Code, Chapter 481, as amended.

(c) Personnel.

(1) Pharmacist-in-charge.

(A) General. Each FEMCF shall have one pharmacist-in-charge who is employed or under contract, at least on a consulting or part-time basis, but may be employed on a full-time basis.

(B) Responsibilities. The pharmacist-in-charge shall have the responsibility for, at a minimum, the following:

(i) establishing specifications for procurement and storage of all materials, including drugs, chemicals, and biologicals;

(ii) participating in the development of a formulary for the FEMCF, subject to approval of the appropriate committee of the FEMCF;

(iii) distributing drugs to be administered to patients pursuant to the practitioner's medication order;

(iv) filling and labeling all containers from which drugs are to be distributed or dispensed;

(v) maintaining and making available a sufficient inventory of antidotes and other emergency drugs, both in the pharmacy and patient care areas, as well as current antidote information, telephone numbers of regional poison control center and other emergency assistance organizations, and such other materials and information as may be deemed necessary by the appropriate committee of the FEMCF;

(vi) maintaining records of all transactions of the FEMCF pharmacy as may be required by applicable state and federal law, and as may be necessary to maintain accurate control over and accountability for all pharmaceutical materials;

(vii) participating in those aspects of the FEMCF's patient care evaluation program which relate to pharmaceutical material utilization and effectiveness;

(viii) participating in teaching and/or research programs in the FEMCF;

(ix) implementing the policies and decisions of the appropriate committee(s) relating to pharmaceutical services of the FEMCF;

(x) providing effective and efficient messenger and delivery service to connect the FEMCF pharmacy with appropriate areas of the FEMCF on a regular basis throughout the normal workday of the FEMCF;

(xi) labeling, storing, and distributing investigational new drugs, including maintaining information in the pharmacy and nursing station where such drugs are being administered, concerning the dosage form, route of administration, strength, actions, uses, side effects, adverse effects, interactions, and symptoms of toxicity of investigational new drugs;

(xii) meeting all inspection and other requirements of the Texas Pharmacy Act and this section; and

(xiii) maintaining records in a data processing system such that the data processing system is in compliance with the requirements for an FEMCF; and

(xiv) ensuring that a pharmacist visits the FEMCF at least once each calendar week that the facility is open.

(2) Consultant pharmacist.

(A) The consultant pharmacist may be the pharmacist-in-charge.

(B) A written contract shall exist between the FEMCF and any consultant pharmacist, and a copy of the written contract shall be made available to the board upon request.

(3) Pharmacists.

(A) General.

(i) The pharmacist-in-charge shall be assisted by a sufficient number of additional licensed pharmacists as may be required to operate the FEMCF pharmacy competently, safely, and adequately to meet the needs of the patients of the facility.

(ii) All pharmacists shall assist the pharmacist-in-charge in meeting the responsibilities as outlined in paragraph (1)(B) of this subsection and in ordering, administering, and accounting for pharmaceutical materials.

(iii) All pharmacists shall be responsible for any delegated act performed by pharmacy technicians or pharmacy technician trainees under his or her supervision.

(iv) All pharmacists while on duty shall be responsible for complying with all state and federal laws or rules governing the practice of pharmacy.

(B) Duties. Duties of the pharmacist-in-charge and all other pharmacists shall include, but need not be limited to, the following:

(i) receiving and interpreting prescription drug orders and oral medication orders and reducing these orders to writing either manually or electronically;

(ii) selecting prescription drugs and/or devices and/or suppliers; and

(iii) interpreting patient profiles.

(C) Special requirements for compounding non-sterile preparations. All pharmacists engaged in compounding non-sterile preparations shall meet the training requirements specified in §291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations).

(4) Pharmacy technicians and pharmacy technician trainees.

(A) General. All pharmacy technicians and pharmacy technician trainees shall meet the training requirements specified in §297.6 of this title (relating to Pharmacy Technician and Pharmacy Technician Trainee Training).

(B) Duties. Pharmacy technicians and pharmacy technician trainees may not perform any of the duties listed in paragraph (3)(B) of this subsection. Duties may include, but need not be limited to, the following functions, under the direct supervision of a pharmacist:

(i) prepacking and labeling unit and multiple dose packages, provided a pharmacist supervises and conducts a final check and affixes his or her name, initials, or electronic signature to the appropriate quality control records prior to distribution;

(ii) preparing, packaging, compounding, or labeling prescription drugs pursuant to medication orders, provided a pharmacist supervises and checks the preparation;

(iii) compounding non-sterile preparations pursuant to medication orders provided the pharmacy technicians or pharmacy

technician trainees have completed the training specified in §291.131 of this title;

(iv) bulk compounding, provided a pharmacist supervises and conducts in-process and final checks and affixes his or her name, initials, or electronic signature to the appropriate quality control records prior to distribution;

(v) distributing routine orders for stock supplies to patient care areas;

(vi) entering medication order and drug distribution information into a data processing system, provided judgmental decisions are not required and a pharmacist checks the accuracy of the information entered into the system prior to releasing the order or in compliance with the absence of pharmacist requirements contained in subsection (d)(6)(D) and (E) of this section;

(vii) maintaining inventories of drug supplies;

(viii) maintaining pharmacy records; and

(ix) loading drugs into an automated medication supply system. For the purpose of this clause, direct supervision may be accomplished by physically present supervision or electronic monitoring by a pharmacist.

(C) Procedures.

(i) Pharmacy technicians and pharmacy technician trainees shall handle medication orders in accordance with standard written procedures and guidelines.

(ii) Pharmacy technicians and pharmacy technician trainees shall handle prescription drug orders in the same manner as pharmacy technicians or pharmacy technician trainees working in a Class A pharmacy.

(D) Special requirements for compounding non-sterile preparations. All pharmacy technicians and pharmacy technician trainees engaged in compounding non-sterile preparations shall meet the training requirements specified in §291.131 of this title.

(5) Owner. The owner of an FEMCF pharmacy shall have responsibility for all administrative and operational functions of the pharmacy. The pharmacist-in-charge may advise the owner on administrative and operational concerns. The owner shall have responsibility for, at a minimum, the following, and if the owner is not a Texas licensed pharmacist, the owner shall consult with the pharmacist-in-charge or another Texas licensed pharmacist:

(A) establishing policies for procurement of prescription drugs and devices and other products dispensed from the FEMCF pharmacy;

(B) establishing and maintaining effective controls against the theft or diversion of prescription drugs;

(C) if the pharmacy uses an automated medication supply system, reviewing and approving all policies and procedures for system operation, safety, security, accuracy and access, patient confidentiality, prevention of unauthorized access, and malfunction;

(D) providing the pharmacy with the necessary equipment and resources commensurate with its level and type of practice; and

(E) establishing policies and procedures regarding maintenance, storage, and retrieval of records in a data processing system such that the system is in compliance with state and federal requirements.

(6) Identification of pharmacy personnel. All pharmacy personnel shall be identified as follows:

(A) Pharmacy technicians. All pharmacy technicians shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacy technician.

(B) Pharmacy technician trainees. All pharmacy technician trainees shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacy technician trainee.

(C) Pharmacist interns. All pharmacist interns shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacist intern.

(D) Pharmacists. All pharmacists shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacist.

(d) Operational standards.

(1) Licensing requirements.

(A) An FEMCF pharmacy shall register annually or biennially with the board on a pharmacy license application provided by the board, following the procedures specified in §291.1 of this title (relating to Pharmacy License Application).

(B) An FEMCF pharmacy which changes ownership shall notify the board within 10 days of the change of ownership and apply for a new and separate license as specified in §291.3 of this title (relating to Required Notifications).

(C) An FEMCF pharmacy which changes location and/or name shall notify the board of the change within 10 days and file for an amended license as specified in §291.3 of this title.

(D) A pharmacy owned by a partnership or corporation which changes managing officers shall notify the board in writing of the names of the new managing officers within 10 days of the change, following the procedures in §291.3 of this title.

(E) An FEMCF pharmacy shall notify the board in writing within 10 days of closing, following the procedures in §291.5 of this title (relating to Closing a Pharmacy).

(F) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged for issuance and renewal of a license and the issuance of an amended license.

(G) A separate license is required for each principal place of business and only one pharmacy license may be issued to a specific location.

(H) An FEMCF pharmacy, which also operates another type of pharmacy which would otherwise be required to be licensed under the Act, §560.051(a)(1), concerning community pharmacy (Class A), is not required to secure a license for the other type of pharmacy; provided, however, such license is required to comply with the provisions of §291.31 of this title (relating to Definitions), §291.32 of this title (relating to Personnel), §291.33 of this title (relating to Operational Standards), §291.34 of this title (relating to Records), and §291.35 of this title (relating to Official Prescription Requirements), to the extent such sections are applicable to the operation of the pharmacy.

(I) An FEMCF pharmacy engaged in the compounding of non-sterile preparations shall comply with the provisions of §291.131 of this title.

(2) Environment.

(A) General requirements.

(i) Each FEMCF shall have a designated work area separate from patient areas, and which shall have space adequate for the size and scope of pharmaceutical services and shall have adequate space and security for the storage of drugs.

(ii) The FEMCF pharmacy shall be arranged in an orderly fashion and shall be kept clean. All required equipment shall be clean and in good operating condition.

(B) Special requirements.

(i) The FEMCF pharmacy shall have locked storage for Schedule II controlled substances and other controlled drugs requiring additional security.

(ii) The FEMCF pharmacy shall have a designated area for the storage of poisons and externals separate from drug storage areas.

(C) Security.

(i) The pharmacy and storage areas for prescription drugs and/or devices shall be enclosed and capable of being locked by key, combination, or other mechanical or electronic means, so as to prohibit access by unauthorized individuals. Only individuals authorized by the pharmacist-in-charge may enter the pharmacy or have access to storage areas for prescription drugs and/or devices.

(ii) The pharmacist-in-charge shall consult with FEMCF personnel with respect to security of the drug storage areas, including provisions for adequate safeguards against theft or diversion of dangerous drugs, controlled substances, and records for such drugs.

(iii) The pharmacy shall have locked storage for Schedule II controlled substances and other drugs requiring additional security.

(3) Equipment and supplies. FEMCFs supplying drugs for outpatient use shall have the following equipment and supplies:

(A) data processing system including a printer or comparable equipment;

(B) adequate supply of child-resistant, moisture-proof, and light-proof containers; and

(C) adequate supply of prescription labels and other applicable identification labels.

(4) Library. A reference library shall be maintained that includes the following in hard copy or electronic format and that pharmacy personnel shall be capable of accessing at all times:

(A) current copies of the following:

(i) Texas Pharmacy Act and rules;

(ii) Texas Dangerous Drug Act and rules;

(iii) Texas Controlled Substances Act and rules; and

(iv) Federal Controlled Substances Act and rules or official publication describing the requirements of the Federal Controlled Substances Act and rules;

(B) at least one current or updated general drug information reference which is required to contain drug interaction information including information needed to determine severity or significance of the interaction and appropriate recommendations or actions to be taken; and

(C) basic antidote information and the telephone number of the nearest regional poison control center.

(5) Drugs.

(A) Procurement, preparation, and storage.

(i) The pharmacist-in-charge shall have the responsibility for the procurement and storage of drugs, but may receive input from other appropriate staff of the facility, relative to such responsibility.

(ii) The pharmacist-in-charge shall have the responsibility for determining specifications of all drugs procured by the facility.

(iii) FEMCF pharmacies may not sell, purchase, trade, or possess prescription drug samples, unless the pharmacy meets the requirements as specified in §291.16 of this title (relating to Samples).

(iv) All drugs shall be stored at the proper temperatures, as defined in the USP/NF and in §291.15 of this title (relating to Storage of Drugs).

(v) Any drug bearing an expiration date may not be dispensed or distributed beyond the expiration date of the drug.

(vi) Outdated drugs shall be removed from dispensing stock and shall be quarantined together until such drugs are disposed of.

(B) Formulary.

(i) A formulary may be developed by an appropriate committee of the FEMCF.

(ii) The pharmacist-in-charge, consultant pharmacist, or designee shall be a full voting member of any committee which involves pharmaceutical services.

(iii) A practitioner may grant approval for pharmacists at the FEMCF to interchange, in accordance with the facility's formulary, for the drugs on the practitioner's medication orders provided:

(I) a formulary has been developed;

(II) the formulary has been approved by the medical staff of the FEMCF;

(III) there is a reasonable method for the practitioner to override any interchange; and

(IV) the practitioner authorizes a pharmacist in the FEMCF to interchange on his/her medication orders in accordance with the facility's formulary through his/her written agreement to abide by the policies and procedures of the medical staff and facility.

(C) Prepackaging and loading drugs into automated medication supply system.

(i) Prepackaging of drugs.

(I) Drugs may be prepackaged in quantities suitable for internal distribution only by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist.

(II) The label of a prepackaged unit shall indicate:

(-a-) brand name and strength of the drug; or if no brand name, then the generic name, strength, and name of the manufacturer or distributor;

(-b-) facility's lot number;

(-c-) expiration date; and

(-d-) quantity of the drug, if quantity is greater than one.

(III) Records of prepackaging shall be maintained to show:

dosage form;

(-b-) facility's lot number;

(-c-) manufacturer or distributor;

(-d-) manufacturer's lot number;

(-e-) expiration date;

(-f-) quantity per prepackaged unit;

(-g-) number of prepackaged units;

(-h-) date packaged;

the packer; and

(-j-) signature or electronic signature of the responsible pharmacist.

(IV) Stock packages, repackaged units, and control records shall be quarantined together until checked/released by the pharmacist.

(ii) Loading bulk unit of use drugs into automated medication supply systems. Automated medication supply systems may be loaded with bulk unit of use drugs only by a pharmacist, by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist, or by a licensed nurse who is authorized by the pharmacist to perform the loading of the automated medication supply system. For the purpose of this clause, direct supervision may be accomplished by physically present supervision or electronic monitoring by a pharmacist. In order for the pharmacist to electronically monitor, the medication supply system must allow for bar code scanning to verify the loading of drugs, and a record of the loading must be maintained by the system and accessible for electronic review by the pharmacist.

(6) Medication orders.

(A) Drugs may be administered to patients in FEMCFs only on the order of a practitioner. No change in the order for drugs may be made without the approval of a practitioner except as authorized by the practitioner in compliance with paragraph (5)(B) of this subsection.

(B) Drugs may be distributed only pursuant to the copy of the practitioner's medication order.

(C) FEMCF pharmacies shall be exempt from the labeling provisions and patient notification requirements of §562.006 and §562.009 of the Act, as respects drugs distributed pursuant to medication orders.

(D) In FEMCFs with a full-time pharmacist, if a practitioner orders a drug for administration to a bona fide patient of the facility when the pharmacy is closed, the following is applicable:

(i) prescription drugs and devices only in sufficient quantities for immediate therapeutic needs of a patient may be removed from the FEMCF pharmacy;

(ii) only a designated licensed nurse or practitioner may remove such drugs and devices;

(iii) a record shall be made at the time of withdrawal by the authorized person removing the drugs and devices. The record shall contain the following information:

(I) name of the patient;

(II) name of device or drug, strength, and dosage form;

(III) dose prescribed;

(IV) quantity withdrawn;

(V) time and date; and

(VI) signature or electronic signature of the person making the withdrawal;

(iv) the medication order in the patient's chart may substitute for such record, provided the medication order meets all the requirements of clause (iii) of this subparagraph;

(v) the pharmacist shall verify the withdrawal of a controlled substance as soon as practical, but in no event more than 72 hours from the time of such withdrawal; and

(vi) the pharmacist shall verify the withdrawal of a dangerous drug at a reasonable interval, but such verification must occur at least once in every calendar week.

(E) In FEMCFs with a part-time or consultant pharmacist, if a practitioner orders a drug for administration to a bona fide patient of the FEMCF when the pharmacist is not on duty, or when the pharmacy is closed, the following is applicable:

(i) prescription drugs and devices only in sufficient quantities for therapeutic needs may be removed from the FEMCF pharmacy;

(ii) only a designated licensed nurse or practitioner may remove such drugs and devices;

(iii) a record shall be made at the time of withdrawal by the authorized person removing the drug or device as described in clauses (6)(D)(iii) and (iv) of this subsection; and

(iv) the pharmacist shall verify withdrawals at a reasonable interval, but such verification must occur at least once in every calendar week that the pharmacy is open.

(7) Floor stock. In facilities using a floor stock method of drug distribution, the pharmacy shall establish designated floor stock areas outside of the central pharmacy where drugs may be stored, in accordance with the pharmacy's policies and procedures. The following is applicable for removing drugs or devices in the absence of a pharmacist:

(A) prescription drugs and devices may be removed from the pharmacy only in the original manufacturer's container or prepackaged container;

(B) only a designated licensed nurse or practitioner may remove such drugs and devices;

(C) a record shall be made at the time of withdrawal by the authorized person removing the drug or device and the record shall contain the following information:

(i) name of the drug, strength, and dosage form;

(ii) quantity removed;

(iii) location of floor stock;

(iv) date and time; and

(v) signature or electronic signature of person making the withdrawal;

(D) the medication order in the patient's chart may substitute for the record required in subparagraph (C) of this paragraph, provided the medication order meets all the requirements of subparagraph (C) of this paragraph; and

(E) if a stored drug or device is returned to the pharmacy from floor stock areas, a record shall be made by the authorized person

returning the drug or device. The record shall contain the following information:

(i) drug name, strength, and dosage form, or device name;

(ii) quantity returned;

(iii) previous floor stock location for the drug or device;

(iv) date and time; and

(v) signature or electronic signature of person returning the drug or device.

(8) Policies and procedures. Written policies and procedures for a drug distribution system, appropriate for the freestanding emergency medical facility, shall be developed and implemented by the pharmacist-in-charge with the advice of the appropriate committee. The written policies and procedures for the drug distribution system shall include, but not be limited to, procedures regarding the following:

(A) controlled substances;

(B) investigational drugs;

(C) prepackaging and manufacturing;

(D) medication errors;

(E) orders of physician or other practitioner;

(F) floor stocks;

(G) adverse drug reactions;

(H) drugs brought into the facility by the patient;

(I) self-administration;

(J) emergency drug tray;

(K) formulary, if applicable;

(L) drug storage areas;

(M) drug samples;

(N) drug product defect reports;

(O) drug recalls;

(P) outdated drugs;

(Q) preparation and distribution of IV admixtures;

(R) procedures for supplying drugs for postoperative use, if applicable;

(S) use of automated medication supply systems;

(T) use of data processing systems; and

(U) drug regimen review.

(9) Drugs supplied for outpatient use. Drugs provided to patients for take home use shall be supplied according to the following procedures.

(A) Drugs may only be supplied to patients who have been admitted to the FEMCF.

(B) Drugs may only be supplied in accordance with the system of control and accountability established for drugs supplied from the FEMCF; such system shall be developed and supervised by the pharmacist-in-charge or staff pharmacist designated by the pharmacist-in-charge.

(C) Only drugs listed on the approved outpatient drug list may be supplied; such list shall be developed by the pharmacist-in-charge and the medical staff and shall consist of drugs of the nature and type to meet the immediate postoperative needs of the FEMCF patient.

(D) Drugs may only be supplied in prepackaged quantities not to exceed a 72-hour supply in suitable containers and appropriately prelabeled (including name, address, and phone number of the facility and necessary auxiliary labels) by the pharmacy, provided, however that topicals and ophthalmics in original manufacturer's containers may be supplied in a quantity exceeding a 72-hour supply.

(E) At the time of delivery of the drug, the practitioner shall complete the label, such that the prescription container bears a label with at least the following information:

- (i) date supplied;
- (ii) name of practitioner;
- (iii) name of patient;
- (iv) directions for use;
- (v) brand name and strength of the drug; or if no brand name, then the generic name of the drug dispensed, strength, and the name of the manufacturer or distributor of the drug; and
- (vi) unique identification number.

(F) After the drug has been labeled, the practitioner or a licensed nurse under the supervision of the practitioner shall give the appropriately labeled, prepackaged medication to the patient.

(G) A perpetual record of drugs which are supplied from the FEMCF shall be maintained which includes:

- (i) name, address, and phone number of the facility;
- (ii) date supplied;
- (iii) name of practitioner;
- (iv) name of patient;
- (v) directions for use;
- (vi) brand name and strength of the drug; or if no brand name, then the generic name of the drug dispensed, strength, and the name of the manufacturer or distributor of the drug; and
- (vii) unique identification number.

(H) The pharmacist-in-charge, or a pharmacist designated by the pharmacist-in-charge, shall review the records at least once in every calendar week that the pharmacy is open.

(10) Drug regimen review.

(A) A pharmacist shall evaluate medication orders and patient medication records for:

- (i) known allergies;
- (ii) rational therapy--contraindications;
- (iii) reasonable dose and route of administration;
- (iv) reasonable directions for use;
- (v) duplication of therapy;
- (vi) drug-drug interactions;
- (vii) drug-food interactions;
- (viii) drug-disease interactions;
- (ix) adverse drug reactions;

(x) proper utilization, including overutilization or underutilization; and

(xi) clinical laboratory or clinical monitoring methods to monitor and evaluate drug effectiveness, side effects, toxicity, or adverse effects, and appropriateness to continued use of the drug in its current regimen.

(B) A retrospective, random drug regimen review as specified in the pharmacy's policies and procedures shall be conducted on a periodic basis to verify proper usage of drugs not to exceed 31 days between such reviews.

(C) Any questions regarding the order must be resolved with the prescriber and a written notation of these discussions made and maintained.

(e) Records.

(1) Maintenance of records.

(A) Every inventory or other record required to be kept under the provisions of this section (relating to Pharmacies Located in a Freestanding Emergency Medical Care Facility (Class F) shall be:

(i) kept by the pharmacy and be available, for at least two years from the date of such inventory or record, for inspecting and copying by the board or its representative, and other authorized local, state, or federal law enforcement agencies; and

(ii) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the board. If the pharmacy maintains the records in an electronic format, the requested records must be provided in a mutually agreeable electronic format if specifically requested by the board or its representative. Failure to provide the records set out in this subsection, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.

(B) Records of controlled substances listed in Schedule II shall be maintained separately and readily retrievable from all other records of the pharmacy.

(C) Records of controlled substances listed in Schedules III - V shall be maintained separately or readily retrievable from all other records of the pharmacy. For purposes of this subparagraph, "readily retrievable" means that the controlled substances shall be asterisked, redlined, or in some other manner readily identifiable apart from all other items appearing on the record.

(D) Records, except when specifically required to be maintained in original or hard copy form, may be maintained in an alternative data retention system, such as a data processing or direct imaging system, provided:

(i) the records in the alternative data retention system contain all of the information required on the manual record; and

(ii) the alternative data retention system is capable of producing a hard copy of the record upon the request of the board, its representative, or other authorized local, state, or federal law enforcement or regulatory agencies.

(E) Controlled substance records shall be maintained in a manner to establish receipt and distribution of all controlled substances.

(F) An FEMCF pharmacy shall maintain a perpetual inventory of controlled substances listed in Schedules II - V which shall be verified for completeness and reconciled at least once in every calendar week that the pharmacy is open.

(G) Distribution records for controlled substances, listed in Schedules II - V, shall include the following information:

- (i) patient's name;
- (ii) practitioner's name who ordered the drug;
- (iii) name of drug, dosage form, and strength;
- (iv) time and date of administration to patient and quantity administered;
- (v) signature or electronic signature of individual administering the controlled substance;
- (vi) returns to the pharmacy; and
- (vii) waste (waste is required to be witnessed and cosigned, manually or electronically, by another individual).

(H) The record required by subparagraph (G) of this paragraph shall be maintained separately from patient records.

(I) A pharmacist shall conduct an audit by randomly comparing the distribution records required by subparagraph (G) of this paragraph with the medication orders in the patient record on a periodic basis to verify proper administration of drugs not to exceed 30 days between such reviews.

(2) Patient records.

(A) Each medication order or set of orders issued together shall bear the following information:

- (i) patient name;
- (ii) drug name, strength, and dosage form;
- (iii) directions for use;
- (iv) date; and
- (v) signature or electronic signature of the practitioner or that of his or her authorized agent, defined as a licensed nurse employee or consultant/full or part-time pharmacist of the FEMCF.

(B) Medication orders shall be maintained with the medication administration record in the medical records of the patient.

(3) General requirements for records maintained in a data processing system.

(A) If an FEMCF pharmacy's data processing system is not in compliance with the board's requirements, the pharmacy must maintain a manual recordkeeping system.

(B) The facility shall maintain a backup copy of information stored in the data processing system using disk, tape, or other electronic backup system and update this backup copy on a regular basis to assure that data is not lost due to system failure.

(C) A pharmacy that changes or discontinues use of a data processing system must:

- (i) transfer the records to the new data processing system; or
- (ii) purge the records to a printout which contains:
 - (I) all of the information required on the original document; or
 - (II) for records of distribution and return for all controlled substances, the same information as required on the audit trail printout as specified in subparagraph (F) of this paragraph. The information on the printout shall be sorted and printed by drug name and list all distributions and returns chronologically.

(D) Information purged from a data processing system must be maintained by the pharmacy for two years from the date of initial entry into the data processing system.

(E) The pharmacist-in-charge shall report to the board in writing any significant loss of information from the data processing system within 10 days of discovery of the loss.

(F) The data processing system shall have the capacity to produce a hard copy printout of an audit trail of drug distribution and return for any strength and dosage form of a drug (by either brand or generic name or both) during a specified time period. This printout shall contain the following information:

- (i) patient's name or patient's facility identification number;
- (ii) prescribing or attending practitioner's name;
- (iii) name, strength, and dosage form of the drug product actually distributed;
- (iv) total quantity distributed from and returned to the pharmacy;
- (v) if not immediately retrievable via electronic image, the following shall also be included on the printout:
 - (I) prescribing or attending practitioner's address; and
 - (II) practitioner's DEA registration number, if the medication order is for a controlled substance.

(G) An audit trail printout for each strength and dosage form of the drugs distributed during the preceding month shall be produced at least monthly and shall be maintained in a separate file at the facility. The information on this printout shall be sorted by drug name and list all distributions/returns for that drug chronologically.

(H) The pharmacy may elect not to produce the monthly audit trail printout if the data processing system has a workable (electronic) data retention system which can produce an audit trail of drug distribution and returns for the preceding two years. The audit trail required in this clause shall be supplied by the pharmacy within 72 hours, if requested by an authorized agent of the board, or other authorized local, state, or federal law enforcement or regulatory agencies.

(I) In the event that an FEMCF pharmacy which uses a data processing system experiences system downtime, the pharmacy must have an auxiliary procedure which will ensure that all data is retained for online data entry as soon as the system is available for use again.

(4) Distribution of controlled substances to another registrant. A pharmacy may distribute controlled substances to a practitioner, another pharmacy, or other registrant, without being registered to distribute, under the following conditions.

(A) The registrant to whom the controlled substance is to be distributed is registered under the Controlled Substances Act to possess that controlled substance.

(B) The total number of dosage units of controlled substances distributed by a pharmacy may not exceed 5.0% of all controlled substances dispensed by the pharmacy during the 12-month period in which the pharmacy is registered; if at any time it does exceed 5.0%, the pharmacy is required to obtain an additional registration to distribute controlled substances.

(C) If the distribution is for a Schedule III, IV, or V controlled substance, a record shall be maintained which indicates:

- (i) the actual date of distribution;
- (ii) the name, strength, and quantity of controlled substances distributed;
- (iii) the name, address, and DEA registration number of the distributing pharmacy; and
- (iv) the name, address, and DEA registration number of the pharmacy, practitioner, or other registrant to whom the controlled substances are distributed.

(D) A pharmacy shall comply with 21 CFR 1305 regarding the DEA order form (DEA 222) requirements when distributing a Schedule II controlled substance.

(5) Other records. Other records to be maintained by the pharmacy include:

(A) a permanent log of the initials or identification codes which identifies each pharmacist by name. The initials or identification code shall be unique to ensure that each pharmacist can be identified, i.e., identical initials or identification codes cannot be used;

(B) suppliers' invoices of dangerous drugs and controlled substances dated and initialed or signed by the person receiving the drugs;

(i) a pharmacist shall verify that the controlled substances listed on the invoices were added to the pharmacy's perpetual inventory by clearly recording his/her initials and the date of review of the perpetual inventory; and

(ii) for controlled substances, the documents retained must contain the name, strength and quantity of controlled substances distributed, and the name, address and DEA number of both registrants; the supplier and the receiving pharmacy;

(C) supplier's credit memos for controlled substances and dangerous drugs;

(D) a copy of inventories required by §291.17 of this title (relating to Inventory Requirements) except that a perpetual inventory of controlled substances listed in Schedule II may be kept in a data processing system if the data processing system is capable of producing a hard copy of the perpetual inventory on site;

(E) reports of surrender or destruction of controlled substances and/or dangerous drugs to an appropriate state or federal agency or reverse distributor;

(F) records of distribution of controlled substances and/or dangerous drugs to other pharmacies, practitioners, or registrants; and

(G) a copy of any notification required by the Texas Pharmacy Act or these rules, including, but not limited to, the following:

- (i) reports of theft or significant loss of controlled substances to DEA and the board;
- (ii) notification of a change in pharmacist-in-charge of a pharmacy; and
- (iii) reports of a fire or other disaster which may affect the strength, purity, or labeling of drugs, medications, devices, or other materials used in the diagnosis or treatment of injury, illness, and disease.

(6) Permission to maintain central records. Any pharmacy that uses a centralized recordkeeping system for invoices and financial data shall comply with the following procedures.

(A) Controlled substance records. Invoices and financial data for controlled substances may be maintained at a central location provided the following conditions are met:

(i) Prior to the initiation of central recordkeeping, the pharmacy submits written notification by registered or certified mail to the divisional director of DEA as required by the Code of Federal Regulations, Title 21, §1304(a), and submits a copy of this written notification to the board. Unless the registrant is informed by the divisional director of DEA that permission to keep central records is denied, the pharmacy may maintain central records commencing 14 days after receipt of notification by the divisional director;

(ii) The pharmacy maintains a copy of the notification required in this subparagraph; and

(iii) The records to be maintained at the central record location shall not include executed DEA order forms, prescription drug orders, or controlled substance inventories, which shall be maintained at the pharmacy.

(B) Dangerous drug records. Invoices and financial data for dangerous drugs may be maintained at a central location.

(C) Access to records. If the records are kept on microfilm, computer media, or in any form requiring special equipment to render the records easily readable, the pharmacy shall provide access to such equipment with the records.

(D) Delivery of records. The pharmacy agrees to deliver all or any part of such records to the pharmacy location within two business days of written request of a board agent or any other authorized official.

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

Filed with the Office of the Secretary of State on August 20, 2021.

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Executive Director

Texas State Board of Pharmacy

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For further information, please call: (512) 305-8010



CHAPTER 295. PHARMACISTS

22 TAC §295.5

The Texas State Board of Pharmacy adopts amendments to §295.5, concerning Pharmacist License or Renewal Fees. These amendments are adopted with changes to the proposed text as published in the June 25, 2021, issue of the *Texas Register* (46 TexReg 3844). The rule will be republished. The Board adjusted the amount of the fees based on updated information.

The amendments increase pharmacist license fees based on expected expenses.

No comments were received.

The amendments are adopted under §§551.002 and 554.051 of the Texas Pharmacy Act (Chapters 551 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by this adoption: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

§295.5. *Pharmacist License or Renewal Fees.*

(a) Biennial Registration. The Texas State Board of Pharmacy shall require biennial renewal of all pharmacist licenses provided under the Pharmacy Act, §559.002.

(b) Initial License Fee.

(1) The fee for the initial license shall be \$338 for a two-year registration.

(2) New pharmacist licenses shall be assigned an expiration date and initial fee shall be prorated based on the assigned expiration date.

(c) Renewal Fee. The fee for biennial renewal of a pharmacist license shall be \$335 for a two-year registration.

(d) Exemption from fee. The license of a pharmacist who has been licensed by the Texas State Board of Pharmacy for at least 50 years or who is at least 72 years old shall be renewed without payment of a fee provided such pharmacist is not actively practicing pharmacy. The renewal certificate of such pharmacist issued by the board shall reflect an inactive status. A person whose license is renewed pursuant to this subsection may not engage in the active practice of pharmacy without first paying the renewal fee as set out in subsection (c) of this section.

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

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CHAPTER 297. PHARMACY TECHNICIANS AND PHARMACY TECHNICIAN TRAINEES

22 TAC §297.4

The Texas State Board of Pharmacy adopts amendments to §297.4, concerning Fees. These amendments are adopted without changes to the proposed text as published in the June 25, 2021, issue of the *Texas Register* (46 TexReg 3845). The rule will not be republished.

The amendments increase pharmacy technician and pharmacy technician trainee registration fees based on expected expenses.

No comments were received.

The amendments are adopted under §§551.002 and 554.051 of the Texas Pharmacy Act (Chapters 551 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by this adoption: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

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

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TITLE 25. HEALTH SERVICES

PART 11. CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CHAPTER 703. GRANTS FOR CANCER PREVENTION AND RESEARCH

25 TAC §703.26

The Cancer Prevention and Research Institute of Texas ("CPRIT" or "the Institute") adopts the amendment to 25 Texas Administrative Code (TAC) §703.26 without changes to the proposed text as published in the June 4, 2021, issue of the *Texas Register* (46 TexReg 3498); therefore, the rule will not be republished. The amendment clarifies that CPRIT may reimburse certain expenses incurred by participants in a cancer clinical trial pursuant to the authority provided by Texas Health and Safety Code Annotated, § 102.203(b).

Reasoned Justification

The amendment to §703.26 makes the Institute's administrative rules consistent with a statutory change to Texas Health and Safety Code Chapter 102 made by the Legislature in 2019. The 86th Legislature amended CPRIT's statute to authorize reimbursement for costs of participation incurred by cancer clinical trial participants, including transportation, lodging, and costs reimbursed under a program established pursuant to Texas Health and Safety Code Annotated, Chapter 50 "Cancer Clinical Trial Participation Program."

Summary of Public Comments and Staff Recommendation

CPRIT did not receive any public comments regarding the amendment to § 703.26; CPRIT staff recommends proceeding with adoption.

Statutory Authority

CPRIT adopts the rule change under the authority of the Texas Health and Safety Code Annotated, § 102.108, which provides

the Institute with broad rule-making authority to administer the chapter, including rules for awarding grants.

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

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TRD-202103279

Heidi McConnell

Chief Operating Officer

Cancer Prevention and Research Institute of Texas

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For further information, please call: (512) 305-8487



TITLE 28. INSURANCE

PART 1. TEXAS DEPARTMENT OF INSURANCE

CHAPTER 21. TRADE PRACTICES

The Commissioner of Insurance adopts the repeal of 28 TAC Chapter 21, Subchapter P, §§21.2401 - 21.2407, relating to Mental Health Parity, and 28 TAC Chapter 21, Subchapter JJ, §§21.4401 - 21.4404, relating to Autism Spectrum Disorder Coverage. The Commissioner also adopts new 28 TAC Chapter 21, Subchapter P, relating to Mental Health and Substance Use Disorder Parity, §§21.2401 - 21.2409, 21.2411, 21.2413, 21.2414, 21.2421 - 21.2427, 21.2431 - 21.2441, 21.2451, and 21.2452, concerning parity between medical/surgical benefits and mental health and substance use disorder (MH/SUD) benefits. The repeals and adoption implement House Bill 10, 85th Legislature, 2017. The repeals are adopted without changes to the proposal published in the February 19, 2021, issue of the *Texas Register* (46 TexReg 1191).

The repealed rules will not be republished. The Commissioner of Insurance adopts §§21.2403, 21.2405, 21.2409, 21.2411, 21.2414, 21.2432, 21.2434, 21.2438 - 21.2440, 21.2451, and 21.2452 without changes to the proposed text published in the February 19, 2021, issue of the *Texas Register*. These rules will not be republished. The Commissioner adopts §§21.2401, 21.2402, 21.2404, 21.2406 - 21.2408, 21.2413, 21.2421 - 21.2427, 21.2431, 21.2433, 21.2435 - 21.2437, and 21.2441 with changes to the proposed text. These rules will be republished.

The Commissioner withdraws the proposal of new §§21.2410, 21.2412, and 21.2453.

REASONED JUSTIFICATION. This rule is required to implement the legislature's directives in HB 10 to health benefit plan issuers (issuers) and the Commissioner. Issuers are to provide benefits and coverage for MH/SUD under the same terms and conditions applicable to the plan's medical/surgical benefits and coverage. An issuer may not impose quantitative or nonquantitative treatment limitations on benefits for a mental health condition or substance use disorder that are generally more restrictive than the limitations imposed on coverage of benefits for medical or surgical expenses. The Commissioner is required to enforce compliance with the legislature's directive to issuers by evaluating the benefits and coverage offered by an issuer's health benefit plan

for quantitative and nonquantitative treatment limitations in several categories:

- (1) in-network and out-of-network inpatient care,
- (2) in-network and out-of-network outpatient care,
- (3) emergency care, and
- (4) prescription drugs.

This rule is designed to provide issuers guidance on compliance with the legislature's directive and to collect information and require issuer analyses of data that will allow the Commissioner to enforce compliance.

Subchapter Name Change. With the adoption of new Subchapter P, the Texas Department of Insurance (TDI) changes the previous name "Mental Health Parity" to "Mental Health and Substance Use Disorder Parity" to reflect that new Subchapter P applies to parity for both mental health and substance use disorders.

Summary of New Subchapter. Insurance Code §1355.255, concerning Compliance, requires the Commissioner to enforce compliance with Insurance Code §1355.254, concerning Coverage for Mental Health Conditions and Substance Use Disorders, by evaluating the benefits and coverage offered by a health benefit plan (plan) for quantitative treatment limitations (QTLs) and nonquantitative treatment limitations (NQTLs). New §§21.2401 - 21.2452 implement Insurance Code Chapter 1355.

Sections 21.2401 - 21.2406 of Division 1 contain general provisions that apply to the entire subchapter. The remaining sections of Division 1, §§21.2407 - 21.2409, 21.2411, 21.2413, and 21.2414, restate (with a few noted exceptions) the federal medical/surgical and MH/SUD parity requirements established in 45 CFR §146.136(b) - (h) (concerning Parity in Mental Health and Substance Use Disorder Benefits) (federal parity rule).

Division 2, consisting of §§21.2421 - 21.2427, addresses requirements for issuers to provide data on plans' claims, utilization reviews, and reimbursement rates.

Division 3, consisting of §§21.2431 - 21.2441, contains requirements for issuers to analyze parity compliance and maintain documentation of their analyses of plans' QTLs and NQTLs. The requirements to perform and document comparative analyses of the design and application of NQTLs are consistent with 42 USC §300gg-26(a)(8) (concerning Parity in Mental Health and Substance Use Disorder Benefits), as added by the Consolidated Appropriations Act, 2021.

Division 4, consisting of §21.2451 and §21.2452, adopts and updates autism spectrum disorder (ASD) rules based on those from repealed Subchapter JJ. Differences between the repealed and new sections reflect that this coverage is subject to Insurance Code Chapter 1355, Subchapter F, concerning Coverage for Mental Health Conditions and Substance Use Disorders.

TDI received written and oral comments on the rule proposal. TDI considered those comments when drafting this adoption.

DIVISION 1. GENERAL PROVISIONS AND PARITY REQUIREMENTS

28 TAC §21.2401 - 21.2409, 21.2411, 21.2413, and 21.2414

Section 21.2401. Section 21.2401 states the purpose and scope of Subchapter P. It explains that the rules are intended to be consistent with Insurance Code provisions on coverage for MH/SUD and with the federal rules implementing the Mental Health Parity

and Addiction Equity Act of 2008 (MHPAEA), found at 45 CFR §146.136 and 45 CFR §146.121. TDI will consider federal guidance and interpretive materials, including bulletins and FAQs on the federal rules, in interpreting and applying this rule. A change to the proposed text is made to clarify a citation to a federal rule.

Section 21.2402. Section 21.2402 states that Subchapter P applies to all plans subject to Insurance Code Chapter 1355, Subchapter F. This includes any plan that provides coverage for treatment expenses incurred as a result of mental health or substance use disorders unless a specific exception applies. TDI makes a change to the citation under subsection (b)(2) as proposed.

Section 21.2403. Section 21.2403 restricts an issuer's limitations on coverage to those limitations that do not violate the parity requirements in Insurance Code Chapter 1355, Subchapter F and 28 TAC Chapter 21, Subchapter P. For example:

(1) Insurance Code §1355.006(b)(2) allows a plan to exclude coverage of a serious mental illness if it results from the illegal use of certain substances. A plan could theoretically exclude all benefits for both medical/surgical and MH/SUD treatments that result from the illegal use of certain substances (if the plan were not otherwise required to cover substance use disorder). But if the plan excludes only benefits for mental illness, the plan would violate parity requirements.

(2) Insurance Code §1355.015(a-1) allows a plan to exclude ASD coverage for people diagnosed at age 10 or older, and §1355.015(c-1) allows a dollar limit for applied behavioral analysis treatment. These limits are unlikely to apply to medical/surgical benefits. A plan may need to remove these limits to comply with parity.

(3) Insurance Code §1355.054 and §§1355.104 - 1355.106 may allow a plan to restrict coverage for mental health treatment in certain types of facilities in a way that it would not restrict comparable coverage for medical/surgical care. If the plan imposes limits for facility treatment for MH/SUD that are more restrictive than those for medical/surgical, it would violate parity requirements.

(4) Insurance Code §1368.005(b) allows a plan to apply less favorable dollar and durational limits if they are "sufficient." Insurance Code §1368.006(b) allows a plan to impose a three-series lifetime limit on treatment for chemical dependency. Less favorable financial requirements and QTLs violate parity if they fail the "substantially all" and "predominant" tests used to assess parity.

(5) Insurance Code §1355.004(a)(3) and Insurance Code §1368.005(a)(2) require that a plan's QTLs be "the same" as for physical illness. But providing an equivalent benefit may violate parity if the financial requirement or limit applied is more restrictive than the "substantially all" and "predominant" tests.

Section 21.2404. Section 21.2404 lists differences between terms used and provisions in Subchapter P and the federal rules. TDI makes changes to the proposed text of this section to conform to the withdrawal of §21.2410 and §21.2412, which provided for an increased cost exemption. TDI also changes the proposed text by updating references to the federal provisions that are not duplicated in this division because there is no analogous Texas law. TDI does not adopt subsection (d) because it referenced the definition of "base period" under §21.2406, which was not adopted, and §21.2412, which is withdrawn in response to comment. Finally, TDI makes two changes to the proposed text to correct punctuation in subsection (a).

Section 21.2405. Section 21.2405 notifies issuers that should there be deficiencies in an issuer's submissions, TDI may require submission of a corrective action plan, and TDI may also require notice to enrollees. The section also provides that a court's invalidation of a provision or application of Subchapter P does not affect or invalidate other provisions or applications of the subchapter.

Section 21.2406. Section 21.2406 defines terms used in Subchapter P and restates the meanings listed in the federal rule. Defined terms not used in Division 1 are meant to help issuers identify the information and data they are required to report in the spreadsheets described in Divisions 2 and 3. In response to comment, TDI makes a change to the proposed definition of "applied behavior analysis." The adopted definition of "applied behavior analysis" is consistent with the practice of applied behavior analysis in Occupations Code §506.003. In response to comment, TDI makes a change to the proposed definition of "reported claims." The change clarifies that reported claims are to be characterized by the date they are received by the issuer. In response to comment, TDI makes changes to the proposed definition of "peer-to-peer review or physician-to-physician review," to indicate that it "may" occur (instead of "must"), and to replace a description of the review requirements with a reference to the statute. Clarifying changes are also made to the proposed definitions of "administrative denial" and "reasonable method." TDI does not adopt the definition of "base period" because, in response to comment, TDI has withdrawn §21.2410 and §21.2412, making the definition no longer necessary; subsequent definitions are renumbered.

Section 21.2407. Section 21.2407 requires parity in aggregate lifetime and annual dollar limits. A plan's aggregate lifetime or annual dollar limits on MH/SUD benefits is limited in proportion to the plan's aggregate limits on medical/surgical limits. The section explains how to determine the applicable proportionality of benefits. In response to comment, TDI makes conforming changes to this section as proposed to reflect the withdrawal of proposed §21.2410 and §21.2412.

Section 21.2408. Section 21.2408 restates, without any changes that affect its meaning, the federal rule titled "Parity Requirements with Respect to Financial Requirements and Treatment Limitations," located at 45 CFR §146.136(c)(1) - (3). Section 21.2408 provides generally that a plan that provides both medical/surgical and MH/SUD benefits may not apply any financial requirement or treatment limitation to MH/SUD benefits that is more restrictive than the comparable limitation applied to substantially all comparable medical/surgical benefits. The rule also includes instructions explaining how to apply the rule and examples of plan terms that do and do not comply with the rule.

Section 21.2409. Section 21.2409 restates, without any changes that affect its meaning, the federal rule titled "Non-quantitative Treatment Limitations," at 45 CFR §146.136(c)(4). The rule provides generally that a plan may only impose an NQTL on an MH/SUD benefit, either by the plan's terms or in its operation, if the NQTL is comparable to and applied no more stringently than the same limitation on comparable medical/surgical benefits. The rule includes instructions that explain how to apply the rule and examples of plan terms that do and do not comply with the rule.

Section 21.2410. TDI withdraws this section in response to a comment that noted that the statute does not support the cost exemption in §21.2412.

Section 21.2411. Section 21.2411 requires that, when asked, an issuer must give an enrollee or contracted provider the plan's criteria for a medical necessity determination for an MH/SUD benefit. It also requires that, when asked, an issuer must give an enrollee the reason for a denial of benefits, consistent with Insurance Code §4201.303, concerning Adverse Determination: Contents of Notice. An issuer that complies with the rule may still need to give an enrollee more information under other federal or state laws.

Section 21.2412. TDI withdraws this section in response to a comment that noted that the statute does not support the cost exemption addressed in the proposed section.

Section 21.2413. Section 21.2413 prohibits an issuer from contracting to provide a plan that does not comply with the parity requirements in §§21.2407 - 21.2409. TDI makes changes to §21.2413 as proposed to remove a reference to an exemption, to conform the section with the withdrawal of proposed §21.2410.

Section 21.2414. Section 21.2414 prohibits a plan from denying benefits it would otherwise provide for treatment of a type of injury, if the injury was the result of domestic violence or a medical condition, including both physical and mental health conditions. This rule applies even if the medical condition was not diagnosed before the injury.

DIVISION 2. PLAN INFORMATION AND DATA COLLECTION

28 TAC §21.2421 - §21.2427

Section 21.2421. Section 21.2421 lists defined terms for Division 2. TDI makes changes to the section as proposed to provide additional clarity on the cited rules for "in-network." TDI also revises the proposed text to include additional examples of place of service codes for "inpatient" and "outpatient." TDI also capitalizes the reference to Division 2.

Section 21.2422. Section 21.2422 sets out the deadline for an issuer to report the data required by Division 2. The section provides that the required information and data are due annually, based on a calendar-year reporting period. In response to comment, TDI makes changes to these deadlines as proposed. Future annual reporting will be made on July 1. This puts the reporting on a slightly offset reporting schedule as compared with other reports due June 1. For 2020 reporting, TDI sets the deadline as December 1, 2021. TDI also makes a change to capitalize the reference to Division 2.

Section 21.2423. Section 21.2423 explains to issuers that they must provide, in a specified template worksheet, information to TDI for each data collection template the issuer provides to TDI. The data to be reported in separate templates is based on the type of plan and the market in which it is offered. The section includes an example (§21.2423(c)) to illustrate the requirements of the rule. TDI changes the name of the data collection template as proposed to be "MH/SUD Parity Rule Division 2 Data Collection Reporting Form."

Section 21.2424. Section 21.2424 requires an issuer to provide issuer information and information on market type, plan type, number of policies for which data is reported, number of covered lives, and premium volume. It also requires issuers providing health plans that are grandfathered under federal rules to report certain data to TDI. TDI changes the name of the data collection template as proposed to conform to the change made in §21.2423. TDI also changes the proposed text to clarify that the plan information should be reported with respect to the policies or contracts for which data is reported. TDI also makes changes

in the worksheet titled "Issuer and Plan Information" to conform to the changes in the rule text.

Section 21.2425. Section 21.2425 requires an issuer to report claims for medical/surgical and MH/SUD benefits on a worksheet titled "Claims and Utilization Review." The rule requires the claims to be separately reported for mental health and substance use disorders. Section 21.2425 sets forth the types of conditions, based on International Classification of Diseases (ICD) diagnosis codes that must be included in the worksheet, and the classifications for the claims to be reported. Section 21.2425 specifies that the classifications are based on inpatient/outpatient status, network status, emergency status, and prescription drug status. In response to comment on other sections, TDI renames the section as proposed to be "Claims and Utilization Review: Reporting Classifications," and renames the worksheet as proposed to be "Claims and Utilization Review." TDI also makes changes to the proposed text to clarify that the requirements apply to both reported claims and requests for utilization review. TDI changes the name of the data collection template to conform to the change made in §21.2423.

Section 21.2426. Section 21.2426 requires an issuer to report its plans' aggregate claims data on a worksheet titled "Claims and Utilization Review" for each of the reporting categories listed in §21.2425. Section 21.2426 provides that the aggregate claims data must be reported for the reporting year. The spreadsheet requires a detailed breakout of all reported claims. In response to comment, TDI makes changes to the rule text as proposed to clarify that the data collection requires both claims and utilization review data. In addition, the rule section as adopted is renamed to be "Claims and Utilization Review: Aggregate Data Fields." Conforming changes are also made to the proposed text of the section to reflect the changes made to the names of the template and the worksheet in §21.2423 and §21.2425. TDI adds the word "and" to §21.2426(2)(L)(iii). TDI also makes changes in the "Claims and Utilization Review" worksheet to conform to the text of the section, including deleting some references to "N/A" in the data columns relating to emergency care. While preauthorization data is not applicable to emergency care, such care may be subject to concurrent or retrospective reviews and appeals of adverse determinations resulting from such reviews.

Section 21.2427. Section 21.2427 requires an issuer to report plans' average reimbursement rate data separately for in-network and out-of-network providers, within the "MH/SUD Parity Rule Division 2 Data Collection Reporting Form" template in a worksheet titled "Reimbursement Rates." TDI makes a conforming change to the proposed text of §21.2427 to reflect the change to the name of the template made in §21.2423. Data is collected for specific types of physicians and mental health and substance use disorder providers. In the worksheet, TDI specifies billing codes and comparative Medicare reimbursement rate data. The spreadsheet includes a column that calculates the percentage of the Medicare reimbursement rate that a plan's reimbursement rate represents. Insurance Code §1355.255 directs the Commissioner to enforce compliance with §1355.254 by evaluating the benefits and coverage offered by a plan for quantitative and nonquantitative treatment limitations. The Commissioner collects reimbursement rate data as part of this enforcement effort. TDI also has authority to collect issuers' reimbursement rates under Insurance Code Chapter 38, Subchapter H. That subchapter also authorizes TDI to publish aggregated data.

DIVISION 3. COMPLIANCE ANALYSES FOR MH/SUD PARITY

28 TAC §§21.2431 - 21.2441

Section 21.2431. Section 21.2431 states the division's overall requirement that issuers perform quantitative and nonquantitative parity analyses for each of their plan designs. Section 21.2431 also advises issuers that they may use an alternative tool to perform their quantitative parity analysis, rather than the template provided on TDI's website, if the issuer demonstrates to TDI's satisfaction that it is using a methodology for the "predominant" and "substantially all" tests that is consistent with §21.2408 and provides the same level of specificity as the QTL template. TDI will assess whether the alternative compliance tool satisfies the requirements of this section at the time TDI requests that the issuer submit its compliance analysis. Section 21.2431 also advises issuers that they may use an alternative tool to perform their nonquantitative parity analysis, rather than the template provided on TDI's website, if TDI is satisfied that it collects the information required to perform each of the four steps stated in §21.2441, and if the issuer can produce documentation that provides the same level of specificity as the NQTL template. TDI anticipates requesting this documentation during market conduct exams. TDI makes a change to the text of this section as proposed by adding a comma between the section headings listed in subsection (b)(1).

Section 21.2432. Section 21.2432 provides deadlines, including phased-in deadlines for nonquantitative parity analyses. Issuers are notified of the requirements they must meet when marketing new plans or materially modifying existing plans.

Section 21.2433. Section 21.2433 informs issuers about the QTL template and instructions on TDI's website that they may use to provide the issuer and plan information required by §§21.2434 - 21.2436. The section also provides instructions on how to perform the compliance analysis for quantitative parity required by §21.2437.

Issuers are advised that they may complete a single analysis for multiple plans with the same plan design, including plans in different markets. Issuers are also informed that they must retain their completed quantitative parity analyses so that those analyses are available to TDI upon request for any plan or plan design that is available for purchase, and for at least five years after coverage terminates for the last enrollee covered. TDI makes a change to the text of this section as proposed to conform to the title of §21.2435.

Section 21.2434. Section 21.2434 requires issuers to provide identifying information for each plan design, the plan's quantitative parity analysis, and market type and plan type. TDI makes changes in the QTL template to conform to the text of the rule.

Section 21.2435. Section 21.2435 requires issuers to explain in detail their quantitative parity analysis methodology and the data sources used in performing their quantitative analyses. If an issuer does not have enough plan-level data to perform the analysis, the issuer must provide an actuarial certification explaining why the substitute data set used for the analysis is reasonable and actuarially appropriate. TDI changes "dataset" to "data set" for consistency within the rule.

Section 21.2436. Section 21.2436 requires issuers to perform quantitative parity analyses for all covered benefits under the plan documents as detailed in the QTL template's covered benefits worksheet.

Section 21.2437. Section 21.2437 requires that issuers, using the worksheets named for each classification and subclassification, perform the quantitative parity "substantially all" and "predominant" tests. TDI makes a change to the QTL template to

provide an explanatory note in the classification worksheets regarding the use of per member per month data.

Section 21.2438. Section 21.2438 provides issuers general instructions to use in performing the nonquantitative parity analyses. Issuers are instructed to use the NQTL template to perform the plan identification and nonquantitative parity compliance analyses required by §21.2440 and §21.2441. Issuers may complete a single analysis for multiple plans that contain an identical set of NQTLs.

Section 21.2439. Section 21.2439 explains generally what NQTLs are and provides a non-exhaustive list of examples.

Section 21.2440. Section 21.2440 requires issuers to provide identifying information for each plan or plan design for their nonquantitative parity analyses.

Section 21.2441. Section 21.2441 requires issuers to identify each NQTL in a plan's documents, and to complete the four-step analysis detailed in the section for each NQTL contained in the plan documents for each plan. The four-step analysis is intended to replicate the Department of Labor's (DOL's) four-step NQTL parity analysis set out in the DOL's 2020 Self-Compliance Tool for the Mental Health Parity and Addiction Equity Act (MHPAEA), found at www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/self-compliance-tool.pdf. In response to comment, TDI makes a clarification to the proposed rule text by replacing the words "the factors" with "each factor."

As adopted, §21.2441(c) states, "Step 2. Within the NQTL Template, in each classification or subclassification worksheet, an issuer must identify each factor considered in the design and application of the NQTL. Illustrative examples of factors are provided in the NQTL template." To be consistent with the "design and application" language in subsection (c), TDI adds "and apply" to the text of subsection (d) as proposed. This change also ensures the rule is consistent with 42 USC §300gg-26(a)(8)(A)(iii), as added by the Consolidated Appropriations Act, 2021. TDI makes clarifying grammatical changes to "Step 1" and "NQTL template" to be consistent with other parts of the rule. TDI makes a change to subsection (d)(5)(B) to move the semicolon outside of the quotation marks. TDI also makes changes in the NQTL template to conform to the text of the rule.

DIVISION 4. AUTISM SPECTRUM DISORDER

28 TAC §§21.2451 - 21.2453

Section 21.2451. Section 21.2451 states that Division 4 applies only to plans that provide coverage for autism spectrum disorder as required by Insurance Code Chapter 1355.

Section 21.2452. Section 21.2452 provides that the section applies only if a plan is subject to both Subchapters A and F of Insurance Code Chapter 1355. This is because the government plans created in Insurance Code Chapters 1575 and 1579, which are subject to Subchapter A, are not subject to Subchapter F. The section then requires that if an issuer's plan includes a treatment limitation that is permissible under Subchapter A but does not satisfy Subchapter F's parity requirement in §1355.254, the issuer must modify its plan to ensure compliance with Subchapter F.

Section 21.2453. TDI withdraws the proposal of §21.2453. The proposed rule revision was intended to clarify that an applied behavior analyst could provide services, but this was superseded by Occupations Code Chapter 506 (Behavior Analysts), enacted

in 2017. Elimination of this provision clarifies that the adopted rule does not depart from statute.

SUMMARY OF COMMENTS AND AGENCY RESPONSE.

Commenters: Commenters in support of the proposal were Autism Society of Texas, Every Texan, La Hacienda Treatment Center, NAMI Texas, and The Kennedy Forum.

Commenters in support of the proposal with changes were Texas Medical Association, Texas Hospital Association, and Meadows Mental Health Policy Institute. Commenters against the proposal were two individuals, America's Health Insurance Plans, and Texas Association of Health Plans.

Comments on proposed rules generally

Comment. Several commenters expressed support for the proposed rules.

Agency Response. TDI thanks the commenters for the support of the proposed rules.

Comment. A commenter with a dispute before TDI's Division of Workers' Compensation relating to the compensability of an injury expressed dissatisfaction over the handling of their matter.

Agency Response. TDI declines to make a change in response to this comment and notes that the commenter's concerns are outside the scope of the rule.

Comment. Two commenters request that TDI pause rulemaking and evaluate the federal MHPAEA law and new provisions passed in December 2021 as part of the Consolidated Appropriations Act of 2021. They state that the new provisions may affect NQTLs and QTLs, and that studying these changes will provide opportunities for efficient and uniform regulatory oversight.

Another commenter states that the suggestion that TDI should wait for forthcoming guidance before requiring insurers to submit parity compliance analyses is a "red herring." The commenter notes that the DOL's requirements are directly aligned with TDI's proposed rule. A commenter notes that insurers have had nearly seven years to comply with the final MHPAEA rule issued in November 2013, and federal statute now requires plans to have a completed parity compliance analysis for each NQTL.

The commenter opposes delaying the adoption of rules. The commenter notes that Congress recently reinforced the step-wise approach in the Consolidated Appropriations Act of 2021. The commenter states that claims by insurers that these requirements are too burdensome or that plans should have more time to comply should be dismissed, particularly in light of the new unambiguous federal requirements and the significant harm to patients when they experience illegal discrimination in mental health and addiction coverage. Federal statute now requires plans to have a completed parity compliance analysis for each NQTL. The commenter states that if submitting these analyses to TDI now is burdensome, it raises significant questions about whether plans are currently complying with existing federal statutory and regulatory requirements.

Agency Response. TDI does not agree that it is necessary to pause or withdraw the rulemaking. Plans can comply with federal MHPAEA law and guidance while responding to the rule's required NQTL and QTL analyses. TDI sees no need to further delay implementation of HB 10. TDI has considered the most recent federal statute and guidance and has determined that the proposed rules are consistent with those requirements and will not result in duplicative efforts. TDI will closely monitor federal

implementation and be ready to provide additional guidance or rulemaking as needed.

Comment. A commenter expresses concern with various theoretical possible coverages or benefits that a plan could exclude or restrict based on statutes that precede HB 10. The commenter refers specifically to the potential to exclude or restrict (1) benefits for both medical/surgical and MH/SUD treatments that result from the illegal use of a controlled substance (Insurance Code §1355.006), (2) autism coverage for people diagnosed at age 10 or older (§1355.015(a-1)), (3) coverage for mental health treatment in certain types of facilities (§1355.106), and (4) changes to the plan benefit intended to avoid the intent of HB 10.

Agency Response. TDI declines to make changes to the proposed rule in response to the comment. Insurance Code Chapter 1355, Subchapter F, supersedes provisions in other parts of the Insurance Code to the extent that those other provisions authorize a limitation that violates parity requirements, including Insurance Code §§ 1355.006, 1355.015(a-1), and 1355.106 as previously referenced by a commenter. This coordination is addressed in §21.2403.

Comment on rule proposal cost note

Comment. A commenter states that its member stakeholders think that TDI's estimates of programmer and programming supervisor costs are very low.

Agency Response. TDI declines to republish the rule proposal and modify the cost note. The salary data used by TDI in its rule proposal came from the DOL's Occupational Employment and Wage Statistics webpage. However, TDI acknowledges that regulated industry and affected stakeholders may have more applicable cost information. TDI sought general stakeholder involvement and specific cost note input prior to proposal, when the initial rule draft was posted on TDI's website for stakeholder review and comment, and all information that TDI received was considered in drafting this rulemaking, including the cost note.

Comments on Division 1

Comments on §21.2406

Comment. A commenter states concerns related to the definition of "applied behavior analysis" in §21.2406. The commenter states that the definition is inaccurate.

Agency Response. TDI agrees to make a change. The definition as proposed mirrored the definition of "applied behavior analysis" in 28 TAC §21.4402, in the rules for autism spectrum disorder coverage. This definition was based on Tricare's usage. Subsequent to that rule adoption, Senate Bill 589, 85th Legislature, 2017, added a provision for the practice of applied behavior analysis in Occupations Code §506.003. TDI changes the definition as proposed to refer to this meaning.

Comment. A commenter states concerns related to the definition of "denial" in §21.2406. The commenter states that this definition combines claim denials and utilization review denials, which are not the same and should not be combined for reporting purposes. The commenter also requests that the rule clarify that administrative denials apply to claims only and not utilization review processes.

Agency Response. TDI declines to make a change to the definition of "denial." The data collection specifically separates data collected about adverse determinations and administrative denials. There is no field that calls for combining those numbers. The definition is instead relevant for other parts of the rule that

speak broadly about both types of denials. TDI agrees that an administrative denial applies only to claims, and it has modified the definition of "administrative denial" as proposed to make this clarification.

Comment. A commenter states concerns related to the definition of "peer-to-peer review or physician-to-physician review" in §21.2406. The commenter requests that the definition be clarified to acknowledge that a peer-to-peer conversation is not required. The commenter notes that statute requires that the health plan must provide a reasonable opportunity for such a discussion but has no control over whether the requesting provider avails itself of the opportunity.

Agency Response. TDI agrees that statute and rules do not require a peer-to-peer review or physician-to-physician review to have occurred, and it has modified the definition as proposed to change "must" to "may." Consistent with 28 TAC §19.1711, relating to written procedures for appeal of adverse determination, the utilization review must afford the provider of record a reasonable opportunity to discuss the plan of treatment for the enrollee with the physician, and TDI assumes that the opportunity is provided in each case. The intention of the rule is to collect data on how frequently the peer-to-peer review actually occurs.

Comment. A commenter objects to the definition of "plan documents" in §21.2406. The commenter contends that including provider contracts and manuals within this definition is incorrect. The commenter states that those documents are not plan documents that affect the benefits provided to enrollees.

Agency Response. TDI disagrees and declines to make a change. Provider contracts and manuals reflect what providers must do to provide covered services. These documents may include NQTLs and affect the quality and scope of networks, and therefore are relevant to assessing parity. The DOL's MHPAEA Self-Compliance Tool specifically states, "NOTE: NQTLs may also be included in other documents, such as internal guidelines or provider contracts."

TDI understands that plans may have confidentiality and market competition concerns, and TDI notes that information held by TDI is subject to the statutory confidentiality protections afforded by Government Code Chapter 552, including §552.110, concerning Confidentiality of Trade Secrets and Certain Commercial or Financial Information.

Comment. A commenter recommends a change to the definition of "reported claims" in §21.2406. The commenter asks that claims be reported based on claim processing date. The commenter represents that until a claim has been processed, health plan systems do not include the data needed for reporting.

Agency Response. The purpose of the data collection is to receive data for a consistent reporting period using a consistent methodology. Using the claim processing date rather than the claim reported date could skew the data because of different issuers' claim payment practices. Texas requires prompt payment of claims, and issuers report prompt pay data based on the date that claims are received.

However, TDI has revised the definition as proposed to clarify that reported claims are those received by the issuer in a year, and to allow issuers to omit data for any claim that is still pending at the time data is submitted. TDI understands concerns regarding sufficient time for claims processing and has adjusted the data collection due date to July 1 for claims received by December 31 of the previous calendar year.

Comments on §21.2412

Comment. A commenter asks for confirmation that the proposed rule does not apply to Medicaid plans.

Agency Response. TDI affirms that the proposed rule does not apply to Medicaid plans.

Comment. A commenter questions whether §21.2412 should be adopted as proposed. The commenter states that Insurance Code Chapter 1355 does not have an increased cost exemption, and that proposed §21.2412 is not grounded in statute and is contrary to the public policy in HB 10. The commenter states that there is concern about unforeseen consequences of the provision. The commenter recommends rule adoption without the exemption, and to allow insurers to provide information to TDI on any cost increase that the commenter believes may justify future legislative consideration of an exemption.

Agency Response. TDI agrees and withdraws §21.2410 and §21.2412.

Comments on Division 2

Comment on §21.2421

Comment. A commenter states concerns related to the definition of "emergency care" in §21.2421. The commenter objects to including services provided in an ambulance in the definition. The commenter notes that most plans subject to the proposed rules are likely HMOs regulated by Insurance Code Chapter 843, or PPOs regulated by Chapter 1301. Because ambulance services are not included in the meaning of "emergency care" under Chapters 843 and 1301, TDI would be exceeding its statutory authority in applying the proposed definition to those plans.

Agency Response. TDI declines to make changes to the proposed rule in response to the comment. TDI agrees that ambulance transportation and services are generally excluded from the definitions of emergency care in Insurance Code Chapters 843 and 1301. However, not all plans subject to the rule are governed under Insurance Code Chapters 843 or 1301. Inclusion of ambulance services within the definition is for data collection purposes. The intent of the inclusion of emergency ambulance services is to identify whether disparities exist that would demonstrate a lack of parity. A more in-depth parity analysis may be warranted, for example, if a health plan denies claims or utilization requests for emergency care more frequently for mental health emergencies as compared with medical emergencies.

Comment on §21.2422

Comment. A commenter objects to having to report on June 1, 2021. The commenter states that health plans will need more time for necessary computer programming and related tasks in order to prepare these reports for submission to TDI. The commenter requests that TDI delay the due date for this report for 2021 and suggests that health plans be given six months from the effective date of the rule.

Agency Response. TDI agrees and has made changes to the proposed text. Data for calendar year 2020 will be due December 1, 2021. In future years, data for the previous calendar year will be due July 1.

Comment on §21.2425

Comment. A commenter requests that plans be allowed to report the total number of office visits and all other subclassifications together. The commenter states that it is administratively

challenging to separate out these subclassifications for MH/SUD services.

Agency Response. TDI declines to make changes to the proposed rule in response to the comment. Billing codes (such as Current Procedural Terminology codes) will allow issuers to distinguish between office visits and other types of outpatient services. Collecting data separately for office visits and all other outpatient services is necessary to ensure consistent data and accommodate issuers' ability to choose to subclassify under §21.2408(c)(3)(C) for the purposes of parity compliance.

Comments on §21.2426

Comment. A commenter states that the proposed section's title is confusing because it refers only to "utilization review," while requiring the reporting of aggregate claim and utilization review data. The commenter requests clarification on whether the intent is to capture claims data for services provided or for prior authorization requests and outcomes only.

Agency Response. TDI agrees and makes changes to the rule text as proposed to clarify that the data collection requires both claims and utilization review data. In addition, the rule section heading as adopted is renamed to be "Claims and Utilization Review: Aggregate Data Fields." TDI also makes conforming changes to the name of the worksheet and the title for §21.2425, "Claims and Utilization Review: Reporting Classifications." These changes more accurately reflect the scope of the data; the first five rows of the worksheet under §21.2426(1) require claims data, while the subsequent rows under §21.2426(2) - (4) require utilization review data.

Comment. A commenter asserts that the rule requires reporting of "administrative UR denials," while TDI has made clear that such denials are not permitted. The commenter states that if a utilization review request was insufficient, then an adverse determination has occurred, triggering appeal requirements. The commenter notes that plans do not track administrative denials of a utilization review separately from adverse determinations because they are not treated differently.

Agency Response. TDI agrees that an administrative denial is not permitted for a utilization review request and believes the commenter misunderstood the data being requested on administrative denials. Under §21.2426(1)(D), issuers must report "the number of reported claims for services or benefits that have been provided . . . that were administratively denied." TDI has modified the section headings as proposed to clarify that claims data, in addition to utilization review data, is being requested.

Comment. A commenter objects to being required to categorize emergency care into either medical/surgical or MH/SUD categories. The commenter represents that the emergency category should be combined for medical/surgical and MH/SUD claims, since it is difficult to determine whether emergency care was for medical or behavioral conditions. The commenter suggests either deletion of this category or that TDI provide additional guidance on this required categorization.

Agency Response. TDI declines to make changes to the proposed rules in response to the comment. In accordance with §21.2425, plans will use ICD diagnosis codes to distinguish between medical/surgical and MH/SUD categories. Since standardized claim forms include a field for ICD diagnosis codes to be identified, this information should be readily available in issuers' claim data.

Comment. A commenter objects to the requirement to segregate data by age bands. The commenter states that this requirement is not authorized by the MHPAEA or state law and creates an additional and unnecessary administrative burden for health plans.

Agency Response. TDI declines to make changes to the proposed rule in response to the comment. TDI collected this information in the previous data collection for HB 10, and health plans were able to provide the requisite breakdowns. Previous analyses have demonstrated that this information can highlight significant disparities and aid in parity compliance and enforcement. TDI disagrees that state law does not authorize this requirement. Age band inclusion will help TDI pinpoint specific areas where disparities exist and more efficiently direct resources for parity investigations. It has already proven to be useful to TDI in evaluating plan compliance with the MH/SUD coverage requirements in Insurance Code Chapter 1355, as required by §1355.255.

Comment. A commenter objects to the collection of data on the number of adverse determinations that were internally appealed that "then received a peer-to-peer or physician-to-physician review." The commenter notes that an appeal does not require an opportunity for a peer-to-peer discussion; rather, an opportunity must be provided prior to adverse determination. The commenter also requests additional guidance to clarify the meaning of a peer-to-peer review.

Agency Response. TDI declines to make changes to the proposed data collection in response to the comment, but has modified the proposed definition of "peer-to-peer review or physician-to-physician review" to clarify the meaning. TDI disagrees that an opportunity for a peer-to-peer review is not required in the context of an internal appeal. In the example of a prior authorization, an opportunity for a peer-to-peer review must be provided before the plan may issue an adverse determination denying the prior authorization. If that initial adverse determination is appealed, the plan can either reverse the initial determination and approve the care or uphold the original decision and issue an adverse determination. Before issuing an adverse determination, the plan must again provide an opportunity for a peer-to-peer review, consistent with Insurance Code §4201.456 and 28 TAC §19.1710. The data requested is for the number of peer-to-peer reviews that actually occur, recognizing that issuers are required to offer them in every case before issuing an adverse determination.

Comment. A commenter objects to reporting of administrative claim denials as part of the data reporting. The commenter states that an administrative claim denial has nothing to do with prior authorization, utilization review, or medical necessity in general. The commenter strongly recommends that the rule not include this reporting category.

Agency Response. TDI declines to make changes to the proposed rules in response to this comment. TDI agrees that an administrative denial is not relevant or permitted in the context of a request for utilization review. Rather, this data is requested only in the context of claims. The data collected on administrative claim denials is relevant for understanding potential parity issues.

Comment on §21.2427

Comment. A commenter requests that TDI pre-populate the reporting forms with the appropriate Medicare reimbursement rate. The commenter states this would save administrative resources and expenses for health plans.

Agency Response. In response to comment, TDI has pre-populated the reporting forms with the appropriate Medicare reimbursement rate for calendar year 2020. Issuers are not responsible under §21.2427 for reporting the appropriate Medicare reimbursement rate. The percentages of Medicare are calculated by the form.

Comments on Division 3

Comment. Two commenters suggest that TDI use the existing NAIC Market Conduct Annual Statement compliance tool. A commenter states that since this tool has already been thoroughly vetted and operationalized, it should be used in lieu of the proposed compliance analysis. The commenter believes this would serve as an effective vehicle for data collection and both commenters state the NAIC tool allows for a more useful baseline of standardized data elements for TDI.

Agency Response. TDI declines to make changes to the proposed rules in response to the comment. TDI has considered the NAIC Market Regulation Handbook, but the tools adopted in Division 3 are more thorough and will better ensure compliance with parity requirements.

Comment. One commenter strongly supports the required NQTL compliance analyses and highlights the importance of determining compliance prospectively. The commenter also requests that TDI better ensure transparency by requiring compliance analyses to be submitted to TDI and made available to the public.

Agency Response. TDI declines to make a change to the proposed rule. Under §21.2431, issuers must provide their compliance analyses upon request. Information held by TDI will be managed consistent with existing statutes, including Government Code Chapter 552.

Comment on §21.2431

Comment. A commenter is concerned that issuers' use of alternative tools for quantitative and nonquantitative analyses will result in the receipt of inconsistent, incomplete, and potentially nonresponsive information. The administrative burden for TDI will also be greatly increased by having to examine analyses, provided through alternative tools, to determine whether those analyses yield information that is specific enough and consistent with the templates, and potentially requiring issuers to re-submit such analyses according to the templates provided. The commenter recommends that issuers be required to use the templates and associated technical instructions published on TDI's website for all quantitative and nonquantitative analyses, as is required for data collection and reporting, and that the option to use alternative tools be removed.

Agency Response. TDI declines to make a change to the proposed rule. When TDI requests an issuer's compliance analyses, staff will evaluate the issuer's tool and confirm that it uses the correct methodology, provides the same level of specificity, and includes all required information, consistent with TDI's QTL and NQTL templates.

Comment on §21.2434

Comment. A commenter objects to having to report separately by market and plan type and strongly recommends that the rules require reporting by legal entity. The commenter represents that this level of collection is prevalent in other states. The commenter states that the level of detailed reporting is overly granular, causing plans with low membership to yield statistically insignificant data.

Agency Response. TDI declines to make changes to the proposed rule in response to comment. However, TDI agrees that it is more efficient for an issuer to combine reporting where applicable information is the same. Under §21.2433(c), issuers may combine the QTL analysis for any plans that have the same plan design and identify the applicable plans consistent with §21.2434(c). Under §21.2438, issuers may complete a single analysis for multiple plans that contain an identical set of NQTLs and identify the applicable plans consistent with §21.2440(c).

Comment on §21.2435

Comment. A commenter requests clarification on whether there is a required review period for claims or other past data under Division 3. If a particular review period is required, the commenter recommends that it be the prior calendar year.

Agency Response. TDI declines to make changes to the proposed rule in response to comment. TDI notes that the proposed definition of "reasonable method" under §21.2406 provides guidance relevant for determining expected payments, and §21.2435(b)(2) allows for flexibility in reporting by the issuer. TDI agrees that the previous calendar year is appropriate if there is sufficient data at the time the issuer is completing the analysis.

Comment on §21.2436

Comment. A commenter recommends that the rule allow health plans to create their own covered benefits list, rather than being held to the specific proposed list.

Agency Response. TDI agrees with the comment but does not make a change to the proposed text or worksheet. The template for covered benefits is blank. Consistent with §21.2436(b), issuers are able to create their own list.

Comment on §21.2439

Comment. A commenter requests clarification that the list of illustrative examples of NQTLs does not require reporting for each of the examples listed.

Agency Response. TDI declines to make changes to the proposed rule in response to comment. The illustrative examples are a non-exhaustive list of NQTLs that are commonly applied. Section 21.2441 makes clear that plans are required to provide the analysis for each NQTL contained in the plan documents.

Comment on §21.2441

Comment. A commenter recommends that the proposed rules be amended to require issuers to identify "all" factors considered or "each" factor considered in the design of the NQTL. The commenter states that issuers often only identify a single factor or example of factors considered.

Agency Response. TDI agrees and has made a change to the proposed text of §21.2441 in response to comment. As adopted, §21.2441(c) states, "Step 2. Within the NQTL Template, in each classification or subclassification worksheet, an issuer must identify each factor considered in the design and application of the NQTL. Illustrative examples of factors are provided in the NQTL template." This change will provide additional clarification.

Comments on Division 4

Comment. An individual expresses concern that including autism spectrum disorder regulations in a rule that also addresses substance use disorder may give the impression that ASD is an acquired condition.

Agency Response. HB 10 requires issuers to provide benefits and coverage for mental health conditions and substance use disorders under the same terms and conditions applicable to the plan's medical and surgical benefits and coverage. The protections apply to all types of mental health conditions, including ASD. TDI agrees that ASD is not an acquired condition, and that insurance coverage is important for helping people with ASD receive the services they need to achieve their full potential.

Comment on §21.2453

Comment. A commenter objects to the proposed text of §21.2453 to the extent that it does not fully capture existing law in Insurance Code §1355.015(b). The commenter states that the proposed language in §21.2453 appears to address only the requirements of §1355.015(b)(1) and (2), and that this could unintentionally be interpreted to remove the important role of the primary care physician. The commenter provides alternate language for TDI to consider.

Agency Response. TDI declines to adopt the specific language suggested. However, TDI has withdrawn proposed §21.2453. The proposed rule revision was intended to clarify that an applied behavior analyst could provide services, but this was superseded by Occupations Code Chapter 506, concerning Behavior Analysts, which was enacted in 2017. Not adopting the proposed amendments to this section ensures that the rule does not depart from statute.

SUBCHAPTER P. MENTAL HEALTH PARITY

28 TAC §§21.2401 - 21.2407

STATUTORY AUTHORITY. The Commissioner adopts the repeal of 28 TAC Subchapter P, §§21.2401 - 21.2407, under Insurance Code §§1355.257, 1355.258, and 36.001.

Insurance Code §1355.257 provides that Chapter 1355, Subchapter F, supplements Subchapters A and B of that chapter, and Chapter 1368, and the rules adopted under those statutes. Insurance Code §1355.257 also provides that the legislature intends that Subchapter A or B of Insurance Code Chapter 1355, Chapter 1368, or a department rule adopted under those statutes, controls over Subchapter F in any circumstance in which those statutes or rules require a benefit that is not required by Subchapter F, or require a more extensive benefit than is required by Subchapter F.

Insurance Code §1355.258 states that the Commissioner is to adopt rules necessary to implement Chapter 1355, Subchapter F.

Insurance Code §36.001 provides that the Commissioner may adopt any rules necessary and appropriate to implement the powers and duties of TDI under the Insurance Code and other laws of this state.

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

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SUBCHAPTER P. MENTAL HEALTH AND SUBSTANCE USE DISORDER PARITY DIVISION 1. GENERAL PROVISIONS AND PARITY REQUIREMENTS

28 TAC §§21.2401 - 21.2409, 21.2411, 21.2413, 21.2414

STATUTORY AUTHORITY. The Commissioner adopts §§21.2401 - 21.2414 under Insurance Code §§1355.255, 1355.257, 1355.258, and 36.001.

Insurance Code §1355.255 directs the Commissioner to enforce compliance with §1355.254 by evaluating the benefits and coverage offered by a plan for quantitative and nonquantitative treatment limitations.

Insurance Code §1355.257 provides that Chapter 1355, Subchapter F, supplements Subchapters A and B of that chapter, and Chapter 1368, and the rules adopted under those statutes. Insurance Code §1355.257 also provides that the legislature intends that Insurance Code Chapter 1355's Subchapter A or B, Chapter 1368, or a department rule adopted under those statutes, control over Subchapter F in any circumstance in which those statutes or rules require a benefit that is not required by Subchapter F, or require a more extensive benefit than is required by Subchapter F.

Insurance Code §1355.258, addressing coverage for mental health conditions and substance use disorders, states that the Commissioner shall adopt rules necessary to implement Chapter 1355, Subchapter F.

Insurance Code §36.001 provides that the Commissioner may adopt any rules necessary and appropriate to implement the powers and duties of TDI under the Insurance Code and other laws of this state.

§21.2401. Purpose and Scope.

This subchapter provides rules to interpret, implement, and enforce Insurance Code Chapter 1355, Subchapter F, concerning Coverage for Mental Health Conditions and Substance Use Disorders. Except as identified in §21.2404 of this title (relating to Differences from Federal Rules), these rules are intended to be consistent with the Insurance Code and to closely track the federal rules found at 45 CFR §146.136 (concerning Parity in Mental Health and Substance Use Disorder Benefits), 45 CFR §146.121(b)(2)(iii) (concerning Prohibiting Discrimination Against Participants and Beneficiaries Based on a Health Factor), and 45 CFR §147.160 (concerning Parity in Mental Health and Substance Use Disorder Benefits) as published in the *Federal Register*, Vol. 78, No. 219 on November 13, 2013.

§21.2402. Applicability.

(a) Plans subject to this subchapter. This subchapter applies to all health benefit plans subject to Insurance Code Chapter 1355, Subchapter F, concerning Coverage for Mental Health Conditions and Substance Use Disorders. Health benefit plans subject to Insurance Code Chapter 1355, Subchapter F, are plans that provide benefits or coverage

for treatment expenses incurred as a result of a mental health condition or offer mental health or substance use disorder benefits, whether as mandatory coverage under Insurance Code Chapter 1355, concerning Benefits for Certain Mental Disorders, or under another Insurance Code chapter, or as optional coverage (for instance, in an individual short-term limited duration plan).

(b) Excepted plans. This subchapter does not apply to a plan that is excepted from:

(1) Insurance Code Chapter 1355, Subchapter F, as identified in Insurance Code §1355.253, concerning Exceptions; or

(2) Insurance Code Chapter 1425, concerning Application of Subtitle to Certain Coverage, as identified in Insurance Code §1425.001, concerning Exemption from Application of Subtitle.

§21.2404. Differences from Federal Rules.

(a) Global substitution of terms. This subchapter substitutes the following terms for terms used in 45 CFR §146.136 (concerning Parity in Mental Health and Substance Use Disorder Benefits) with no change in meaning:

(1) the term "enrollees" is substituted for the term "participants and beneficiaries";

(2) the term "health benefit plan" is substituted for the terms "group health plan" (or health insurance coverage offered in connection with such plans) and "plan or coverage"; and

(3) the terms "requirement" or "requirements" are substituted for the terms "rule" or "rules."

(b) Omission of federal provisions. The following federal provisions are not duplicated in this division either because they were superseded by a later federal rule or there is no analogous Texas law, or because they are otherwise captured in this subchapter:

(1) 45 CFR §146.136(b)(1)(ii), which addresses exemptions;

(2) 45 CFR §146.136(c)(5), which addresses exemptions;

(3) 45 CFR §146.136(f), which addresses small employer exemption; and

(4) 45 CFR §146.136(g), which addresses increased cost exemption.

(c) Substitutions for federal provisions. Where a state requirement exists, a corresponding but incongruent federal provision has been omitted. Specifically, §21.2411 of this title (relating to Availability of Plan Information) replaces the federal provision at 45 CFR §146.136(d)(2), which addresses reason for any denial. In addition, a portion of 45 CFR §146.136(d)(3), which addresses provisions of other law, has been omitted.

§21.2406. Definitions.

Definitions. For purposes of this subchapter, the following terms have the meanings indicated, except where the context clearly indicates otherwise:

(1) Administrative denial--A denial of a claim that is not an adverse determination, including, but not limited to, denials of claims for noncovered benefits, duplicate claims, incorrect billing, and because an individual is not an enrollee.

(2) Adverse determination--A determination by a health benefit plan or utilization review agent that health care services or benefits provided or proposed to be provided to an enrollee are not medically necessary, appropriate, or are experimental or investigational. Consistent with Insurance Code Chapter 1369, concerning

Benefits Related to Prescription Drugs and Devices and Related Services, the following are adverse determinations:

(A) a denial of a fail-first (or step therapy) protocol exception request; and

(B) an issuer's refusal to treat the drug as a covered benefit, if an enrollee's physician has determined that a drug is medically necessary and the drug is not included in the enrollee's plan formulary.

(3) Aggregate lifetime dollar limit--A dollar limitation on the total amount of specified benefits that may be paid under a health benefit plan for any coverage unit.

(4) Allowed amount--The dollar amount covered under the plan for a particular service or benefit, including the amount of cost sharing owed by the enrollee and the amount to be paid by the plan. This term refers both to the contracted amount for in-network services or benefits and the amount designated by the plan for out-of-network services or benefits.

(5) Annual dollar limit--A dollar limitation on the total amount of specified benefits that may be paid in a 12-month period under a health benefit plan for any coverage unit.

(6) Applied behavior analysis--The design, implementation, and evaluation of instructional and environmental modifications to produce socially significant improvements in human behavior that is consistent with the practice of applied behavior analysis as addressed in Occupations Code §506.003.

(7) Approved claim--A claim for a service or benefit that is determined, at initial review or upon receipt of additional information, to be covered and payable at the plan's allowed amount.

(8) Concurrent review--A form of utilization review for ongoing health care or for an extension of treatment beyond previously approved health care.

(9) Coverage unit--Coverage unit as described in §21.2408(a)(4) of this title (relating to Parity Requirements with Respect to Financial Requirements and Treatment Limitations).

(10) Cumulative financial requirements--Financial requirements that determine whether or to what extent benefits are provided based on accumulated amounts and include deductibles and out-of-pocket maximums. Cumulative financial requirements do not include aggregate lifetime or annual dollar limits.

(11) Cumulative quantitative treatment limitations--Treatment limitations that determine whether or to what extent benefits are provided based on accumulated amounts, such as annual or lifetime day or visit limits. The term includes a deductible, a copayment, coinsurance, or another out-of-pocket expense or annual or lifetime limit, or another financial requirement.

(12) Denial--An administrative denial or an adverse determination.

(13) Fail-first or step therapy--A treatment protocol that requires an enrollee to use a prescription drug or sequence of prescription drugs other than the drug that the enrollee's physician recommends for the enrollee's treatment before the health benefit plan provides coverage for the recommended drug.

(14) Financial requirements--Plan deductibles, copayments, coinsurance, or out-of-pocket maximums. Financial requirements do not include aggregate lifetime or annual dollar limits.

(15) Health benefit plan or plan--A plan that is subject to Insurance Code Chapter 1355, Subchapter F, concerning Coverage for Mental Health Conditions and Substance Use Disorders.

(16) Independent review--A system for final administrative review by an independent review organization (IRO) of an adverse determination regarding the medical necessity, the appropriateness, or the experimental or investigational nature of health care services or benefits.

(17) Individual market--Health benefit plans subject to Insurance Code Chapter 1355, Subchapter F, that are bought on an individual or family basis in which the contract holder is also personally enrolled under the plan, other than in connection with a group health plan.

(18) Internal appeal--A formal process by which an enrollee, an individual acting on behalf of an enrollee, or an enrollee's provider of record may request reconsideration of an adverse determination.

(19) Large group market--Health benefit plans subject to Insurance Code Chapter 1355, Subchapter F, that are sold to groups that have 51 or more members, whether through an employer or through an association.

(20) Market type--Individual, small group, or large group market.

(21) Medical or surgical (medical/surgical) benefit--A benefit with respect to an item or service for medical conditions or surgical procedures, as defined under the terms of the health benefit plan and in accordance with applicable federal and state law, but does not include mental health or substance use disorder benefits. Any condition defined by a plan as being or as not being a medical/surgical condition must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most recent edition of the ICD or state guidelines).

(22) Mental health benefit--A benefit with respect to an item or service for a mental health condition, as defined under the terms of a health benefit plan and in accordance with applicable federal and state law. Any condition defined by a health benefit plan as being or as not being a mental health condition must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most recent edition of the *Diagnostic and Statistical Manual of Mental Disorders (DSM)*, the most recent edition of the ICD, or state guidelines).

(23) NQTL--Nonquantitative treatment limitation.

(24) Peer-to-peer review or physician-to-physician review--A utilization review process that may occur before an adverse determination is issued by a utilization review agent, consistent with Insurance Code §4201.206, concerning Opportunity to Discuss Treatment Before Adverse Determination.

(25) Plan design--A plan's discrete package of benefits, cost-sharing structure, provider network, plan type, quantitative treatment limitations, and nonquantitative treatment limitations.

(26) Plan documents--All instruments under which a plan is established or operated, including, but not limited to, policies, certificates of coverage, contracts of insurance, evidences of coverage, provider contracts, provider manuals, internal guidelines and procedures, medical guidelines, and other documents used in making claims determinations and conducting utilization reviews. Instruments under which the plan is established or operated includes the processes, strategies, evidentiary standards, and other factors used to apply a nonquantitative treatment limitation (NQTL) with respect to medical/surgical benefits and mental health/substance use disorder (MH/SUD) benefits under the plan.

(27) Plan type--A preferred provider organization (PPO) plan, exclusive provider organization (EPO) plan, health maintenance organization (HMO) plan, health maintenance organization-point of service (HMO-POS) plan, and indemnity policy.

(28) Preauthorization or prior authorization--A utilization review process in which an issuer conditions coverage of a health care service, benefit, or prescription drug on the issuer's approval of the provider's request to provide an enrollee the service, benefit, or drug. For purposes of this rule:

(A) preauthorization includes reauthorization of services or benefits that had received preauthorization, but for which the approval period has lapsed;

(B) preauthorization does not include utilization review needed to reauthorize ongoing services or benefits (concurrent review); and

(C) a request for preauthorization is one received during the reporting period, regardless of the date the claim is incurred.

(29) Prescription drugs--Drugs covered under a plan's prescription drug benefit.

(30) QTL--Quantitative treatment limitation.

(31) Reasonable method--To determine the dollar amount or the per member per month amount of plan payments for the substantially all or predominant analyses required by §21.2408 of this title, reasonable methods are:

(A) a projection based on claims data for the plan or the plan design, if there is sufficient claims data for a reasonable projection of future claims costs; or

(B) a projection based on appropriate and sufficient data (such as data from other similarly structured plans with similar demographics) to perform the analysis in compliance with applicable Actuarial Standards of Practice set by the Actuarial Standards Board if:

(i) there is not enough claims data;

(ii) the plan significantly changed its benefit package;

(iii) the plan experienced a significant workforce change that would impact claims costs; or

(iv) the group health plan (or the plan design) is new.

(32) Reported claims--Claims that are received by an issuer in a year, regardless of the incurred date, the final decision date, or a claim's pending status. For example, claims reported in 2020 could include claims incurred in 2019, claims with final decisions made in the first few months of 2020, or claims awaiting a determination.

(33) Retrospective review--The process of reviewing the medical necessity and reasonableness of health care that has been provided to an enrollee.

(34) Small group market--Health benefit plans subject to Insurance Code Chapter 1355, Subchapter F, that are sold to groups that have at least two but no more than 50 members.

(35) Substance use disorder benefit--A benefit with respect to an item, treatment, or service for a substance use disorder, as defined under the terms of a health benefit plan and in accordance with applicable federal and state law. Any disorder defined by the plan as being or as not being a substance use disorder must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the DSM, the most recent edition of the ICD, or state guidelines).

(36) Treatment limitations--This term includes limits on benefits based on the frequency of treatment, number of visits, days of coverage, days in a waiting period, or other similar limits on the scope or duration of treatment. Treatment limitations include both quantitative treatment limitations (QTLs), which are expressed numerically (such as 50 outpatient visits per year), and NQTLs, which otherwise limit the scope or duration of benefits for treatment under a plan. (An illustrative list of NQTLs is provided in §21.2409(b) of this title (relating to Nonquantitative Treatment Limitations).) A permanent exclusion of all benefits for a particular condition or disorder, however, is not a treatment limitation for purposes of this definition.

(37) Utilization review--A system for prospective, concurrent, or retrospective review of the medical necessity or appropriateness of health care services or benefits and a system for prospective, concurrent, or retrospective review to determine the experimental or investigational nature of health care services or benefits. The term does not include a review in response to an elective request for clarification of coverage.

§21.2407. Parity Requirements with Respect to Aggregate Lifetime and Annual Dollar Limits.

This section details application of the parity requirements under this subchapter with respect to aggregate lifetime and annual dollar limits that may be permitted by state or federal law.

(1) General parity requirement. A health benefit plan that provides both medical/surgical benefits and MH/SUD benefits must comply with paragraph (2), (3), or (5) of this section, as applicable.

(2) Plan with no limit or limits on less than one-third of all medical/surgical benefits. If a health benefit plan does not include an aggregate lifetime or annual dollar limit on any medical/surgical benefits or includes an aggregate lifetime or dollar limit that applies to less than one-third of all medical/surgical benefits, it may not impose an aggregate lifetime or annual dollar limit, respectively, on mental health or substance use disorder benefits.

(3) Plan with a limit on at least two-thirds of all medical/surgical benefits. If a health benefit plan includes an aggregate lifetime or annual dollar limit on at least two-thirds of all medical/surgical benefits, it must either:

(A) apply the aggregate lifetime or annual dollar limit both to the medical/surgical benefits to which the limit would otherwise apply and to MH/SUD benefits in a manner that does not distinguish between the medical/surgical benefits and MH/SUD benefits; or

(B) not include an aggregate lifetime or annual dollar limit on mental health or substance use disorder benefits that is less than the aggregate lifetime or annual dollar limit, respectively, on medical/surgical benefits. (Some cumulative financial requirements and cumulative quantitative treatment limitations other than aggregate lifetime or annual dollar limits are prohibited in §21.2408 of this title (relating to Parity Requirements with Respect to Financial Requirements and Treatment Limitations).)

(4) Determining one-third and two-thirds of all medical/surgical benefits. For purposes of this section, the determination of whether the portion of medical/surgical benefits subject to an aggregate lifetime or annual dollar limit represents one-third or two-thirds of all medical/surgical benefits is based on the dollar amount of all plan payments for medical/surgical benefits expected to be paid under the plan for the plan year (or for the portion of the plan year after a change in plan benefits that affects the applicability of the aggregate lifetime or annual dollar limits). Any reasonable method may be used to determine whether the dollar amount expected to be paid under the

plan will constitute one-third or two-thirds of the dollar amount of all plan payments for medical/surgical benefits.

(5) Plan not described in paragraph (2) or (3) of this section.

(A) In general. A health benefit plan that is not described in paragraph (2) or (3) of this section with respect to aggregate lifetime or annual dollar limits on medical/surgical benefits, must either:

(i) impose no aggregate lifetime or annual dollar limit, as appropriate, on mental health or substance use disorder benefits; or

(ii) impose an aggregate lifetime or annual dollar limit on mental health or substance use disorder benefits that is no less than an average limit calculated for medical/surgical benefits in the following manner. The average limit is calculated by taking into account the weighted average of the aggregate lifetime or annual dollar limits, as appropriate, that are applicable to the categories of medical/surgical benefits. Limits based on delivery systems, such as inpatient/outpatient treatment or normal treatment of common, low-cost conditions (such as treatment of normal births), do not constitute categories for purposes of this clause. In addition, for purposes of determining weighted averages, any benefits that are not within a category that is subject to a separately designated dollar limit under the plan are taken into account as a single separate category by using an estimate of the upper limit on the dollar amount that a plan may reasonably be expected to incur with respect to such benefits, taking into account any other applicable restrictions under the plan.

(B) Weighting. For purposes of this paragraph, the weighting applicable to any category of medical/surgical benefits is determined in the manner set forth in paragraph (4) of this section for determining one-third or two-thirds of all medical/surgical benefits.

§21.2408. Parity Requirements with Respect to Financial Requirements and Treatment Limitations.

(a) Clarification of terms.

(1) Classification of benefits. When reference is made in this subchapter to a classification of benefits, the term "classification" means a classification as described in subsection (b)(2) of this section.

(2) Type of financial requirement or treatment limitation. When reference is made in this subchapter to a type of financial requirement or treatment limitation, the reference to type means its nature. Different types of financial requirements include deductibles, copayments, coinsurance, and out-of-pocket maximums. Different types of quantitative treatment limitations include annual, episode, and lifetime day and visit limits. An illustrative list of nonquantitative treatment limitations is provided in §21.2409(b) of this title (relating to Nonquantitative Treatment Limitations).

(3) Level of a type of financial requirement or treatment limitation. When reference is made in this subchapter to a level of a type of financial requirement or treatment limitation, "level" refers to the magnitude of the type of financial requirement or treatment limitation. For example, different levels of coinsurance include 20% and 30%, different levels of a copayment include \$15 and \$20, different levels of a deductible include \$250 and \$500, and different levels of an episode limit include 21 inpatient days per episode and 30 inpatient days per episode.

(4) Coverage unit. When reference is made in this subchapter to a coverage unit, "coverage unit" refers to the way in which a health benefit plan groups individuals for purposes of determining benefits, or premiums or contributions. For example, different coverage units include self-only, family, and employee-plus-spouse.

(b) General parity requirement.

(1) General requirement. A health benefit plan that provides both medical/surgical benefits and mental health or substance use disorder benefits may not apply any financial requirement or treatment limitation to mental health or substance use disorder benefits in any classification that is more restrictive than the predominant financial requirement or treatment limitation of that type applied to substantially all medical/surgical benefits in the same classification. Whether a financial requirement or treatment limitation is a predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in a classification is determined separately for each type of financial requirement or treatment limitation. The application of the requirements of this subsection to financial requirements and quantitative treatment limitations is addressed in subsection (c) of this section; the application of the requirements of this subsection to nonquantitative treatment limitations is addressed in §21.2409 of this title.

(2) Classifications of benefits used for applying requirements.

(A) In general. If a health benefit plan provides mental health or substance use disorder benefits in any classification of benefits described in this subparagraph, mental health or substance use disorder benefits must be provided in every classification in which medical/surgical benefits are provided. In determining the classification in which a particular benefit belongs, a health benefit plan must apply the same standards to medical/surgical benefits and to mental health or substance use disorder benefits. To the extent that a health benefit plan provides benefits in a classification and imposes any separate financial requirement or treatment limitation (or separate level of a financial requirement or treatment limitation) for benefits in the classification, the requirements of this subsection apply separately with respect to that classification for all financial requirements or treatment limitations (illustrated in examples in paragraph (2)(C) of this subsection). The following classifications of benefits are the only classifications used in applying the requirements of this subsection:

(i) An "inpatient, in-network" classification is for benefits furnished on an inpatient basis and within a network of providers established or recognized under a health benefit plan. Special requirements for plans with multiple network tiers are addressed in subsection (c)(3) of this section.

(ii) An "inpatient, out-of-network" classification is for benefits furnished on an inpatient basis and outside any network of providers established or recognized under a health benefit plan. This classification includes inpatient benefits under a health benefit plan that has no network of providers.

(iii) An "outpatient, in-network" classification is for benefits furnished on an outpatient basis and within a network of providers established or recognized under a health benefit plan. Special requirements for office visits and plans with multiple network tiers are addressed in subsection (c)(3) of this section.

(iv) An "outpatient, out-of-network" classification is for benefits furnished on an outpatient basis and outside any network of providers established or recognized under a health benefit plan. This classification includes outpatient benefits under a health benefit plan that has no network of providers. Special requirements for office visits are addressed in subsection (c)(3) of this section.

(v) An "emergency care" classification is for benefits for emergency care.

(vi) A "prescription drug" classification is for benefits for prescription drugs. See special requirements for multi-tiered prescription drug benefits in subsection (c)(3) of this section.

(B) Application to out-of-network providers. Application to out-of-network providers is addressed in subparagraph (A) of this paragraph, under which a health benefit plan that provides mental health or substance use disorder benefits in any classification of benefits must provide mental health or substance use disorder benefits in every classification in which medical/surgical benefits are provided, including out-of-network classifications.

(C) Examples. The requirements of this paragraph are illustrated by examples provided in the figure §21.2408(b)(2)(C). In each example, the health benefit plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits.

Figure: 28 TAC §21.2408(b)(2)(C)

(c) Financial requirements and quantitative treatment limitations.

(1) Determining "substantially all" and "predominant."

(A) Substantially all. For purposes of this section, a type of financial requirement or quantitative treatment limitation is considered to apply to substantially all medical/surgical benefits in a classification of benefits if it applies to at least two-thirds of all medical/surgical benefits in that classification. (For this purpose, benefits expressed as subject to a zero level of a type of financial requirement are treated as benefits not subject to that type of financial requirement, and benefits expressed as subject to a quantitative treatment limitation that is unlimited are treated as benefits not subject to that type of quantitative treatment limitation.) If a type of financial requirement or quantitative treatment limitation does not apply to at least two-thirds of all medical/surgical benefits in a classification, then that type cannot be applied to mental health or substance use disorder benefits in that classification.

(B) Predominant.

(i) If a type of financial requirement or quantitative treatment limitation applies to at least two-thirds of all medical/surgical benefits in a classification as determined under subparagraph (A) of this paragraph, the level of the financial requirement or quantitative treatment limitation that is considered the predominant level of that type in a classification of benefits is the level that applies to more than one-half of medical/surgical benefits in that classification subject to the financial requirement or quantitative treatment limitation.

(ii) If, with respect to a type of financial requirement or quantitative treatment limitation that applies to at least two-thirds of all medical/surgical benefits in a classification, there is no single level that applies to more than one-half of medical/surgical benefits in the classification subject to the financial requirement or quantitative treatment limitation, the plan may combine levels until the combination of levels applies to more than one-half of medical/surgical benefits subject to the financial requirement or quantitative treatment limitation in the classification. The least restrictive level within the combination is considered the predominant level of that type in the classification. (For this purpose, a plan may combine the most restrictive levels first, with each less restrictive level added to the combination until the combination applies to more than one-half of the benefits subject to the financial requirement or treatment limitation.)

(C) Portion based on plan payments. For purposes of this section, the determination of the portion of medical/surgical benefits in a classification of benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation) is based on the dollar

amount of all plan payments for medical/surgical benefits in the classification expected to be paid under the plan for the plan year (for the portion of the plan year after a change in plan benefits that affects the applicability of the financial requirement or quantitative treatment limitation).

(D) Clarifications for certain threshold requirements. For any deductible, the dollar amount of plan payments includes all plan payments with respect to claims that would be subject to the deductible if it had not been satisfied. For any out-of-pocket maximum, the dollar amount of plan payments includes all plan payments associated with out-of-pocket payments that are taken into account toward the out-of-pocket maximum, as well as all plan payments associated with out-of-pocket payments that would have been made toward the out-of-pocket maximum if it had not been satisfied.

(E) Determining the dollar amount of plan payments. Subject to subparagraph (D) of this paragraph, any reasonable method may be used to determine the dollar amount expected to be paid under a plan for medical/surgical benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation).

(2) Application to different coverage units. If a health benefit plan applies different levels of a financial requirement or quantitative treatment limitation to different coverage units in a classification of medical/surgical benefits, the predominant level that applies to substantially all medical/surgical benefits in the classification is determined separately for each coverage unit.

(3) Special requirements.

(A) Multi-tiered prescription drug benefits. If a health benefit plan applies different levels of financial requirements to different tiers of prescription drug benefits based on reasonable factors determined in accordance with the requirements in §21.2409(a) of this title and without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits, the health benefit plan satisfies the parity requirements of this section with respect to prescription drug benefits. Reasonable factors include cost, efficacy, generic versus brand name, and mail order versus pharmacy pick-up.

(B) Multiple network tiers. If a health benefit plan provides benefits through multiple tiers of in-network providers (such as an in-network tier of preferred providers with more generous cost-sharing to participants than a separate in-network tier of participating providers), the plan may divide its benefits furnished on an in-network basis into subclassifications that reflect network tiers, if the tiering is based on reasonable factors determined in accordance with the requirements in §21.2409(a) of this title (such as quality, performance, and market standards) and without regard to whether a provider provides services with respect to medical/surgical benefits or mental health or substance use disorder benefits. After the subclassifications are established, the issuer may not impose any financial requirement or treatment limitation on mental health or substance use disorder benefits in any subclassification that is more restrictive than the predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in the subclassification using the methodology in subsection (c)(1) of this section.

(C) Subclassifications permitted for office visits, separate from other outpatient services. For purposes of applying the financial requirement and treatment limitation requirements of this section, a plan may divide its benefits furnished on an outpatient basis into the two subclassifications described in this subparagraph. After the subclassifications are established, the plan may not impose any financial requirement or quantitative treatment limitation on mental health or

substance use disorder benefits in any subclassification that is more restrictive than the predominant financial requirement or quantitative treatment limitation that applies to substantially all medical/surgical benefits in the subclassification using the methodology in paragraph (1) of this subsection. Subclassifications other than these special requirements, such as separate subclassifications for generalists and specialists, are not permitted. The two subclassifications permitted under this subparagraph are:

(i) office visits (such as physician visits), and

(ii) all other outpatient items and services (such as outpatient surgery, facility charges for day treatment centers, laboratory charges, or other medical items).

(4) Examples. The requirements of paragraph (3)(A) - (C) of this subsection are illustrated by examples provided in figure 28 TAC §21.2408(c)(4). In each example, the health benefit plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits. Figure: 28 TAC §21.2408(c)(4)

(5) No separate cumulative financial requirements or cumulative quantitative treatment limitations.

(A) A health benefit plan may not apply any cumulative financial requirement or cumulative quantitative treatment limitation for mental health or substance use disorder benefits in a classification that accumulates separately from any established for medical/surgical benefits in the same classification.

(B) The requirements of this paragraph are illustrated by examples provided in figure 28 TAC §21.2408(c)(5)(B). Figure: 28 TAC §21.2408(c)(5)(B)

§21.2413. Sale of Nonparity Health Benefit Plans.

An issuer may not sell a health benefit plan, policy, certificate, or contract of insurance that fails to comply with §21.2407 of this title (relating to Parity Requirements with Respect to Aggregate Lifetime and Annual Dollar Limits), §21.2408 of this title (relating to Parity Requirements with Respect to Financial Requirements and Treatment Limitations), and §21.2409 of this title (relating to Nonquantitative Treatment Limitations).

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

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For further information, please call: (512) 676-6584



DIVISION 2. PLAN INFORMATION AND DATA COLLECTION

28 TAC §§21.2421 - 21.2427

STATUTORY AUTHORITY. The Commissioner adopts §§21.2421 - 21.2427 under Insurance Code §§843.151, 846.005, 1202.051, 1251.008, 1271.004, 1355.257, 1355.258, 1501.010, and 36.001.

Insurance Code §843.151, addressing health maintenance organizations' group health plans, provides that the Commissioner may adopt reasonable rules as necessary and proper to meet the requirements of federal law and regulations.

Insurance Code §846.005, addressing multiple employer welfare arrangements' health benefit plans, provides that the Commissioner shall adopt rules necessary to meet the minimum requirements of federal law and regulations.

Insurance Code §1202.051, addressing individual health benefit plans, requires that the Commissioner adopt rules necessary to meet the minimum requirements of federal law, including regulations.

Insurance Code §1251.008, addressing group and blanket health benefit plans, provides that the Commissioner may adopt rules necessary to administer Chapter 1251, concerning Group and Blanket Health Insurance.

Insurance Code §1271.004, addressing health maintenance organizations' individual health care plans, provides that the Commissioner may adopt rules necessary to meet the minimum requirements of federal law, including regulations.

Insurance Code §1355.257 provides that Chapter 1355, Subchapter F, supplements Subchapters A and B of that chapter, and Chapter 1368, and the rules adopted under those statutes. Insurance Code §1355.257 also provides that the legislature intends that Insurance Code Chapter 1355's Subchapter A or B, Chapter 1368, or a department rule adopted under those statutes, control over Subchapter F in any circumstance in which those statutes or rules require a benefit that is not required by Subchapter F, or require a more extensive benefit than is required by Subchapter F.

Insurance Code §1355.258, addressing coverage for mental health conditions and substance use disorders, requires that the Commissioner adopt rules necessary to implement Chapter 1355, Subchapter F.

Insurance Code §1501.010, addressing employers' group health plans, provides that the Commissioner may adopt rules necessary to meet the minimum requirements of federal law, including regulations.

Insurance Code §36.001 provides that the Commissioner may adopt any rules necessary and appropriate to implement the powers and duties of TDI under the Insurance Code and other laws of this state.

§21.2421. Definitions - Division 2.

Definitions for Division 2. For purposes of Division 2 of this subchapter, the following terms have the meanings indicated, except where the context clearly indicates otherwise:

(1) Emergency care--A health care service or benefit:

(A) provided in an air, land, or water ambulance, and that is emergency care as defined under Insurance Code Chapter 1201; or

(B) that meets a plan's applicable statutory definition of emergency care in Insurance Code Chapters 843, 1201, or 1301, or emergency care as required in Insurance Code §1271.155, provided in a hospital emergency facility, licensed freestanding emergency medical care facility, community mental health center, or comparable emergency facility.

(2) In-network--Care covered under the plan's in-network benefit, including care provided by:

(A) an in-network provider; or

(B) an out-of-network provider as required by Insurance Code Chapters 1271 and 1301, and §3.3708 (relating to Payment of Certain Basic Benefit Claims and Related Disclosures), §3.3725 (relating to Payment of Certain Out-of-Network Claims) of this title, and §11.1611 (relating to Out-of-Network Claims; Non-Network Physicians and Providers) of this title.

(3) Inpatient--Care provided on an inpatient basis. Inpatient health care services or benefits are provided in an inpatient facility, including, but not limited to, those identified in CMS Form 1500 POS Codes 21 (Inpatient Hospital (other than psychiatric)), 31 (Skilled Nursing Facility), 32 (Nursing Facility), 34 (Hospice), 51 (Inpatient Psychiatric Facility), 54 (Intermediate Care Facility/Individuals with Intellectual Disabilities), 55 (Residential Substance Abuse Treatment Facility), 56 (Psychiatric Residential Treatment Center), and 61 (Comprehensive Inpatient Rehabilitation Facility).

(4) Office visit--A medical/surgical or mental health/substance use disorder (MH/SUD) service or benefit received in an office, including, but not limited to, those identified in CMS Form 1500 POS Code 11 (Office).

(5) Outpatient--Care provided on an outpatient basis. Outpatient health care services or benefits are provided in an outpatient setting other than an office visit, including, but not limited to, those identified in CMS Form 1500 POS Codes 17 (Walk-in Retail Health Clinic), 18 (Place of Employment/Worksite), 19 (Off Campus - Outpatient Hospital), 20 (Urgent Care Facility), 22 (On Campus - Outpatient Hospital), 24 (Ambulatory Surgical Center), 49 (Independent Clinic), 52 (Psychiatric Facility - Partial Hospitalization), 53 (Community Mental Health Center), 57 (Non-residential Substance Abuse Treatment Facility), 62 (Comprehensive Outpatient Rehabilitation Facility), 65 (End-Stage Renal Disease Treatment Facility), and 72 (Rural Health Clinic).

(6) Out-of-network--Care covered under the plan's out-of-network benefit, and all care under an indemnity plan or other health benefit plan that has no network of providers. Care provided by an out-of-network provider that is covered under the plan's in-network benefit is not out-of-network care.

§21.2422. Deadline for Reporting Data.

Annual reporting. The information and data an issuer must report as required by Division 2 of this subchapter are due annually.

(1) Each reporting period is a calendar year.

(2) The first reporting date for this subchapter is December 1, 2021, for data from January 1, 2020, through December 31, 2020.

(3) An issuer's annual reports for calendar year 2021 and subsequent reporting periods are due not later than July 1 following the reporting period.

§21.2423. Collecting and Reporting Data.

(a) Requirement to collect and report data. An issuer must collect and report the data required by this division for each applicable health benefit plan using the data collection template titled "MH/SUD Parity Rule Division 2 Data Collection Reporting Form," consisting of multiple worksheets, published on TDI's website.

(b) Separate templates required. For each combination of plan type and market type the issuer offers, the data must be reported in a separate template with its own worksheets.

(c) Example. An example of how subsection (b) of this section would be satisfied is that an issuer offering PPO plans and EPO plans in the individual, small, and large group markets will submit a separate

template with its own worksheets for its PPO individual plans, its PPO small group plans, and its PPO large group plans, and another three files for its EPO plans, for a total submission of six templates with their own worksheets.

§21.2424. Issuer and Plan Information.

(a) Identifying issuer information. For each data collection template an issuer provides to TDI under §21.2423 of this title (relating to Collecting and Reporting Data), within the "MH/SUD Parity Rule Division 2 Data Collection Reporting Form" template, in the worksheet titled "Issuer and Plan Information," an issuer must provide the:

- (1) issuer name;
- (2) NAIC number, or if none, issuer license number;
- (3) reporting year;
- (4) submission date;
- (5) contact name;
- (6) title;
- (7) phone number; and
- (8) email address.

(b) Identifying plan information. In the "Issuer and Plan Information" worksheet, an issuer must identify the:

- (1) market type;
- (2) plan type;
- (3) number of policies or contracts for which data is reported;
- (4) number of covered lives for which data is reported; and
- (5) premium volume for policies or contracts for which data is reported.

(c) Information on grandfathered coverage. In the "Issuer and Plan Information" worksheet, an issuer must specify whether it has any plans subject to this rule that provide grandfathered coverage, as defined in 45 CFR §147.140 (concerning Preservation of Right to Maintain Existing Coverage). If so, the issuer must identify the:

- (1) number of policies or contracts that provide grandfathered coverage;
- (2) number of covered lives under grandfathered coverage; and
- (3) premium volume for grandfathered policies or contracts.

§21.2425. Claims and Utilization Review: Reporting Classifications.

(a) Separate reporting. Within the "MH/SUD Parity Rule Division 2 Data Collection Reporting Form" template, in the worksheet titled "Claims and Utilization Review," an issuer must separately report claims and requests for utilization review for medical/surgical and MH/SUD.

(b) ICD diagnosis codes. In the worksheet titled "Claims and Utilization Review," all claims and utilization review requests with mental, behavioral, and neurodevelopmental disorder diagnosis codes in the International Classification of Diseases and Related Health Problems should be categorized as MH/SUD. Claims and utilization review requests with all other ICD diagnostic codes should be categorized as medical/surgical.

(c) Reporting classifications. Claims and requests for utilization review are to be identified in the worksheet as belonging in one the following reporting classifications:

- (1) inpatient, in-network;
- (2) inpatient, out-of-network;
- (3) outpatient, in-network, consisting of:
 - (A) office visits; and
 - (B) all other;
- (4) outpatient, out-of-network, consisting of:
 - (A) office visits; and
 - (B) all other;
- (5) emergency; and
- (6) prescription drugs.

(d) Unneeded information. Where appropriate, an issuer may enter "N/A" in the worksheet. For example, indemnity plans will not have data for in-network classifications, and HMOs with no POS component and EPOs will not have data for out-of-network classifications. An issuer of those plans may therefore enter N/A where that data is requested.

§21.2426. Claims and Utilization Review: Aggregate Data Fields.

Within the "MH/SUD Parity Rule Division 2 Data Collection Reporting Form" template, in the worksheet titled "Claims and Utilization Review," for medical/surgical, MH/SUD, and for each of the classifications listed in §21.2425(c) of this title (relating to Claims and Utilization Review: Reporting Classifications), an issuer must provide the following aggregate claims and utilization review data for the reporting year:

- (1) the number of reported claims for services or benefits that have been provided:
 - (A) in total;
 - (B) by out-of-network providers that were covered as in-network benefits;
 - (C) that were approved;
 - (D) that were administratively denied; and
 - (E) that were adversely determined;
- (2) the number of utilization reviews, including:
 - (A) preauthorization requests for:
 - (i) children ages 0 - 12;
 - (ii) adolescents ages 13 - 17; and
 - (iii) adults;
 - (B) preauthorization requests approved for:
 - (i) children ages 0 - 12;
 - (ii) adolescents ages 13 - 17; and
 - (iii) adults;
 - (C) preauthorization requests that received a peer-to-peer or physician-to-physician review for:
 - (i) children ages 0 - 12;
 - (ii) adolescents ages 13 - 17; and
 - (iii) adults;

(D) preauthorization requests that were subject to a fail-first or step therapy requirement;

(E) preauthorization requests that were adversely determined for:

- (i) children ages 0 - 12;
- (ii) adolescents ages 13 - 17; and
- (iii) adults;

(F) concurrent reviews for:

- (i) children ages 0 - 12;
- (ii) adolescents ages 13 - 17; and
- (iii) adults;

(G) concurrent reviews approved for:

- (i) children ages 0 - 12;
- (ii) adolescents ages 13 - 17; and
- (iii) adults;

(H) concurrent reviews that received a peer-to-peer or physician-to-physician review for:

- (i) children ages 0 - 12;
- (ii) adolescents ages 13 - 17; and
- (iii) adults;

(I) concurrent reviews that were adversely determined for:

- (i) children ages 0 - 12;
- (ii) adolescents ages 13 - 17; and
- (iii) adults;

(J) retrospective reviews for:

- (i) children ages 0 - 12;
- (ii) adolescents ages 13 - 17; and
- (iii) adults;

(K) retrospective reviews that were approved for:

- (i) children ages 0 - 12;
- (ii) adolescents ages 13 - 17; and
- (iii) adults;

(L) retrospective reviews that received a peer-to-peer or physician-to-physician review for:

- (i) children ages 0 - 12;
- (ii) adolescents ages 13 - 17; and
- (iii) adults; and

(M) retrospective reviews that were adversely determined for:

- (i) children ages 0 - 12;
- (ii) adolescents ages 13 - 17; and
- (iii) adults;

(3) the number of adverse determinations that were internally appealed that:

(A) then received a peer-to-peer or physician-to-physician review on internal appeal;

(B) were again adversely determined on internal appeal; and

(C) were reversed on internal appeal; and

(4) the number of adverse determinations independently reviewed that were:

(A) upheld on independent review; and

(B) reversed on independent review.

§21.2427. *Plan Reimbursement Rates Compared with Medicare Rates.*

(a) Reporting worksheet. An issuer must report the data required by this section within the "MH/SUD Parity Rule Division 2 Data Collection Reporting Form" template in the worksheet titled "Reimbursement Rates."

(b) Categories of providers and billing codes. An issuer must report average plan reimbursement rates separately for in-network and out-of-network providers for services provided by the following categories of providers for the billing codes specified by TDI in the worksheet:

- (1) orthopedic surgeons;
- (2) cardiologists;
- (3) internists;
- (4) endocrinologists;
- (5) gastroenterologists;
- (6) neurologists;
- (7) pediatricians;
- (8) dermatologists;
- (9) psychiatrists;
- (10) psychologists;
- (11) licensed clinical social workers;
- (12) podiatrists;
- (13) chiropractors;
- (14) occupational therapists; and
- (15) physical therapists.

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

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For further information, please call: (512) 676-6584

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DIVISION 3. COMPLIANCE ANALYSIS FOR
MH/SUD PARITY

28 TAC §§21.2431 - 21.2441

STATUTORY AUTHORITY. The Commissioner adopts §§21.2431 - 21.2441 under Insurance Code §§1355.257, 1355.258, and 36.001.

Insurance Code §1355.257 provides that Chapter 1355, Subchapter F, supplements Subchapters A and B of that chapter, and Chapter 1368, and the rules adopted under those statutes. Insurance Code §1355.257 also provides that the legislature intends that Insurance Code Chapter 1355's Subchapter A or B, Chapter 1368, or a department rule adopted under those statutes, control over Subchapter F in any circumstance in which those statutes or rules require a benefit that is not required by Subchapter F, or require a more extensive benefit than is required by Subchapter F.

Insurance Code §1355.258, addressing coverage for mental health conditions and substance use disorders, requires that the Commissioner adopt rules necessary to implement Chapter 1355, Subchapter F.

Insurance Code §36.001 provides that the Commissioner may adopt any rules necessary and appropriate to implement the powers and duties of TDI under the Insurance Code and other laws of this state.

§21.2431. Required Analyses for Quantitative and Nonquantitative Parity; Alternative Tools.

(a) QTL and NQTL templates.

(1) For purposes of this division, "QTL template" is the template titled "Compliance Analysis for Quantitative Parity" and its associated technical instructions, available on TDI's website.

(2) For purposes of this division, "NQTL template" is the template titled "Compliance Analysis for Nonquantitative Parity" and its associated technical instructions, available on TDI's website.

(b) Analyses of quantitative and nonquantitative parity.

(1) An issuer must analyze each health benefit plan to determine whether its plan design complies with the quantitative parity requirements in §§21.2433 - 21.2437 of this title (relating to Compliance Analysis for Quantitative Parity: General Requirements, Quantitative Parity Analysis: Issuer and Plan Information, Quantitative Parity Analysis: Methodology for Determining Expected Payments, Quantitative Parity Analysis: Covered Benefits, and Quantitative Parity Analysis: "Substantially All" and "Predominant" Tests), using the QTL template, except as permitted by subsection (c) of this section.

(2) An issuer must analyze each health benefit plan to determine whether its plan design complies with the nonquantitative parity requirements in §§21.2438 - 21.2441 of this title (relating to Compliance Analysis for Nonquantitative Parity: General Instructions, Nonquantitative Treatment Limitations Generally, Nonquantitative Parity Analysis: Issuer and Plan Information, and Four-Step Analysis of Nonquantitative Treatment Limitations), using the NQTL template, except as permitted by subsection (d) of this section.

(c) Alternative tool for quantitative parity analysis. An issuer may use an alternative quantitative parity analysis tool instead of the QTL template if the issuer demonstrates to TDI's satisfaction that it is using a methodology for the "predominant" and "substantially all" tests that is consistent with §21.2408 of this title (relating to Parity Requirements with Respect to Financial Requirements and Treatment Limitations).

(1) Upon request by TDI, an issuer must produce documentation that provides the same level of specificity as the QTL template.

(2) TDI will assess whether the alternative compliance tool satisfies the requirements of this section at the time TDI requests that the issuer submit its compliance analysis.

(d) Alternative tool for nonquantitative parity analysis. An issuer may use an alternative tool instead of the NQTL template if the issuer demonstrates to TDI's satisfaction that the alternative tool contains the information required for each step of the four-step process stated in §21.2441 of this title.

(1) Upon request by TDI, an issuer must produce documentation that provides the same level of specificity as the NQTL template.

(2) TDI will assess whether the alternative tool satisfies the requirements of this section at the time TDI requests that the issuer submit its compliance analysis.

§21.2433. Compliance Analysis for Quantitative Parity: General Requirements.

(a) Template and instructions. Except as provided in §21.2431 of this title (relating to Required Analyses for Quantitative and Nonquantitative Parity; Alternative Tools), an issuer must use the QTL template and associated technical instructions to:

(1) provide the information required by §21.2434 of this title (relating to Quantitative Parity Analysis: Issuer and Plan Information), §21.2435 of this title (relating to Quantitative Parity Analysis: Methodology for Determining Expected Payments), and §21.2436 of this title (relating to Quantitative Parity Analysis: Covered Benefits); and

(2) perform the compliance analysis for quantitative parity required by §21.2437 of this title (relating to Quantitative Parity Analysis: "Substantially All" and "Predominant" Tests).

(b) Template programming. TDI may program the QTL template to populate some information and complete some steps of the analysis automatically.

(c) Compliance analysis for plans with the same plan design. An issuer may complete a single analysis for multiple plans with the same plan design.

(d) Retention of completed template. An issuer must retain its completed quantitative parity analysis for each plan, plan design, or modified plan design. The completed analysis must be available to TDI upon request for any plan or plan design that is available for purchase, and for at least five years after coverage terminates for the last enrollee covered.

(e) Version control. The issuer must use a version control system to ensure that the issuer can provide to TDI upon request the version of the completed analysis that applied to a plan on a given date.

§21.2435. Quantitative Parity Analysis: Methodology for Determining Expected Payments.

(a) Expected payment methodology. Within each QTL template, in the worksheet titled "Expected Payment Methodology," an issuer must provide an explanation of the methodology that describes the underlying data used to determine the total payments of each benefit in the quantitative analyses, such as the steps, data, and assumptions used to calculate or project expected payments. The description must demonstrate that:

(1) the quantitative analysis is based on the total allowed amounts (not limited to the portion paid by the plan), projected for the applicable plan year;

(2) the quantitative analysis for each classification and subclassification, if applicable, accounts for all expected payments for all covered medical/surgical benefits under the plan or plan design; and

(3) a reasonable method was used to determine the expected payment amount. An issuer must document the assumptions used in choosing a data set and making projections.

(b) Data sources. An issuer must clearly describe the following information, in addition to any other relevant information:

(1) the specific plans or other sources of claims data used to determine the expected payment amounts for the analysis;

(2) the time period of the claims data--for example, calendar years 2018 and 2019; and

(3) what adjustments, if any, were made to the data or payment projections.

(c) Insufficient plan-level data. If data other than plan-level data was used for the analysis, an issuer must submit a separate actuarial certification addressing:

(1) the sufficiency and credibility of plan-level data; and

(2) why the substitute data set used for the analyses is reasonable and actuarially appropriate, including a description of any assumptions used in choosing the data and making projections.

§21.2436. Quantitative Parity Analysis: Covered Benefits.

(a) General information. Within each QTL template, in the worksheet titled "Covered Benefits," an issuer must identify:

(1) whether outpatient benefits are subclassified into "office visit" and "other;"

(2) whether the plan or plan design has a tiered network; and

(3) if the plan or plan design has a tiered network, the number of tiers.

(b) List of covered benefits. In the worksheet titled "Covered Benefits," an issuer must list each benefit covered by the plan or plan design, including all benefits listed in the schedule of benefits and the policy, certificate, evidence of coverage, or contract of insurance. Covered benefits must be repeated as needed to list each benefit on separate lines, based on:

(1) network;

(2) types and levels of applicable financial requirements and QTLs; and

(3) classification or subclassification, as applicable.

(c) Combining covered benefits. Covered benefits that have the same QTLs may be combined for the purposes of the QTL analysis;

(d) Examples. The examples in this subsection illustrate the requirements of subsections (b) and (c) of this section.

(1) Example 1. If a plan or plan design covers the first office visit with \$0 cost sharing, and subsequent office visits are subject to coinsurance, then each level of cost sharing must be listed on a separate line.

(2) Example 2. If a plan or plan design covers occupational therapy for both medical/surgical and MH/SUD diagnoses, then occupational therapy must be listed on separate lines for each.

(3) Example 3. If a plan or plan design covers physical therapy, occupational therapy, and speech therapy subject to identical QTLs, then the covered benefits may be combined in a single line.

(4) Example 4. If a plan or plan design applies identical types and levels of QTLs to all in-network medical/surgical and MH/SUD covered benefits, then all in-network medical/surgical

covered benefits may be combined in a single line and all in-network MH/SUD covered benefits may be combined in a single line, for a total of two lines of covered benefits in each classification worksheet.

(e) Categorization, classification, and subclassification of covered benefits. For each covered benefit, the issuer must:

(1) categorize the covered benefit, consistent with the definitions of "medical/surgical benefit," "mental health benefit," and "substance use disorder benefit" in §21.2406 of this title (relating to Definitions), as medical/surgical or MH/SUD;

(2) classify the covered benefit consistent with §21.2408(b)(2)(A)(i) - (vi) of this title (relating to Parity Requirements with Respect to Financial Requirements and Treatment Limitations) as:

(A) inpatient, in-network;

(B) inpatient, out-of-network;

(C) outpatient, in-network;

(D) outpatient, out-of-network; and

(E) emergency care;

(3) if the issuer uses multiple network tiers, add separate subclassifications for in-network classifications, consistent with §21.2408(c)(3)(B) of this title; and

(4) if applicable to outpatient benefits, subclassify the covered benefit, consistent with §21.2408(c)(3)(C) of this title, as:

(A) outpatient, in-network including, if applicable, separate identification of:

(i) outpatient in-network office visits; and

(ii) all other outpatient in-network benefits; and

(B) outpatient, out-of-network, including, if applicable, separate identification of:

(i) outpatient out-of-network office visits; and

(ii) all other outpatient out-of-network benefits.

(f) Methodology for categorizing covered benefits. Within the QTL template, in the worksheet titled "Categorization Methodology," an issuer must provide an explanation of the methodology used to categorize a covered benefit as a mental health benefit, medical/surgical benefit, or substance use disorder benefit. If a plan defines a condition as a mental health condition, substance use disorder, or medical or surgical condition, it must categorize benefits for those conditions in the same way for purposes of this rule. For example, if a plan defines unspecified dementia as a mental health condition, it must categorize benefits for unspecified dementia as mental health benefits. An issuer must apply the same categorization for both the QTL and NQTL analyses.

(g) Methodology for classifying and subclassifying covered benefits. Within the QTL template, in the worksheet titled "Classification Methodology," an issuer must provide an explanation of the methodology used to classify and subclassify covered benefits, consistent with §21.2408(b)(2) and (c)(3) of this title. In determining the classification in which a particular benefit belongs, an issuer must apply the same standards to medical/surgical benefits as to MH/SUD benefits. Plans and issuers must assign covered intermediate MH/SUD benefits (such as residential treatment, partial hospitalization, and intensive outpatient treatment) to the existing six classifications in the same way that they assign intermediate medical/surgical benefits to these classifications. For example, if a plan classifies care in skilled nursing facilities

and rehabilitation hospitals for medical/surgical benefits as inpatient benefits, it must classify covered care in residential treatment facilities for MH/SUD benefits as inpatient benefits. If a plan treats home health care as an outpatient benefit, then any covered intensive outpatient MH/SUD services and partial hospitalization must be considered outpatient benefits as well. An issuer must apply its methodology consistently when classifying covered benefits and use the same classification for both the QTL and NQTL analyses.

§21.2437. Quantitative Parity Analysis: "Substantially All" and "Predominant" Tests.

(a) Separate worksheet and analysis for each classification and subclassification. Within the QTL template are separate worksheets, named for each classification or subclassification (classification worksheets) identified in §21.2436(e) of this title (relating to Quantitative Parity Analysis: Covered Benefits). If an issuer's plan design applies a QTL or financial requirement to a MH/SUD benefit in a given classification or subclassification, the issuer must document, in the applicable classification worksheet, the following:

(1) in Column 1 of each classification worksheet: the dollar amount or per member per month amount of all plan payments expected to be paid under the plan for the plan year consistent with §21.2408(c)(1)(C) - (E) of this title (relating to Parity Requirements with Respect to Financial Requirements and Treatment Limitations);

(2) in Column 2 of each classification worksheet: whether a copay applies and, if applicable, the copay amount;

(3) in Column 3 of each classification worksheet: whether a coinsurance applies and, if applicable, the coinsurance percentage amount;

(4) in Column 4 of each classification worksheet: whether a deductible applies and, if applicable, the deductible amount;

(5) in Column 5 of each classification worksheet: whether a session limit applies and, if applicable, the session limit quantity; and

(6) in Column 6 of each classification worksheet: whether a day limit applies to each service category and, if applicable, the day limit quantity.

(b) "Substantially all" test. Consistent with §21.2408(c)(1)(A) of this title, an issuer must perform the following calculations separately in each classification worksheet to determine whether a QTL or financial requirement that applies to MH/SUD benefits also applies to substantially all medical/surgical benefits.

(1) To calculate the aggregate total of expected plan payments for medical/surgical benefits in the classification worksheet, add the dollar amounts listed in every row of Column 1.

(2) To determine whether a copay applies to substantially all medical/surgical benefits in the classification worksheet:

(A) for every row in Column 2 of the worksheet with a copay amount listed greater than \$0, add the expected plan payment amounts for the benefit listed in Column 1 of that row; and

(B) divide the amount in subsection (b)(2)(A) of this section by the aggregate total calculated under subsection (b)(1) of this section.

(3) To determine whether a coinsurance applies to substantially all medical/surgical benefits in the classification worksheet:

(A) for every row in Column 3 of the worksheet with an enrollee coinsurance amount listed greater than \$0, add the expected plan payment amounts for the benefit listed in Column 1 of that row; and

(B) divide the amount addressed in subsection (b)(3)(A) of this section by the aggregate total calculated under subsection (b)(1) of this section.

(4) To determine whether a deductible applies to substantially all medical/surgical benefits in the classification worksheet:

(A) for every row in Column 4 of the worksheet with a deductible amount listed greater than \$0, add the expected plan payment amounts for the benefit listed in Column 1 of that row; and

(B) divide the amount addressed in subsection (b)(4)(A) of this section by the aggregate total calculated under subsection (b)(1) of this section.

(5) To determine whether a session limit applies to substantially all medical/surgical benefits in the classification worksheet:

(A) for every row in Column 5 of the worksheet with a session limit listed that is less than unlimited, add the expected plan payment amounts for the benefit category listed in Column 1 of that row; and

(B) divide the amount addressed in subsection (b)(5)(A) of this section by the aggregate total calculated under subsection (b)(1) of this section.

(6) To determine whether a day limit applies to substantially all medical/surgical benefits in the classification worksheet:

(A) for every row in Column 6 of the worksheet with a day limit listed that is less than unlimited, add the expected plan payment amounts for the benefit listed in Column 1 of that row; and

(B) divide the amount addressed in subsection (b)(6)(A) of this section by the aggregate total calculated under subsection (b)(1) of this section.

(7) If the amount calculated under any of the paragraphs in subsections (b)(2) - (b)(6) of this section is less than two-thirds on any of the classification worksheets, the financial requirement or quantitative treatment limitation in that paragraph fails the "substantially all" test under §21.2408(c)(1)(A) of this title and cannot be applied to a MH/SUD benefit.

(c) "Predominant" test. Consistent with §21.2408(c)(1)(B) of this title, the issuer must separately perform the following calculations in each classification worksheet, as applicable, to determine whether the level of a type of quantitative treatment limitation or financial requirement that satisfied the "substantially all" test in subsection (b) of this section is no less favorable than the predominant quantitative treatment limitation or financial requirement that applies to medical/surgical benefits.

(1) Calculate the aggregate total of expected plan payments for medical/surgical benefits within each classification or subclassification that is subject to a particular type of financial requirement or quantitative treatment limitation. Separately, in Columns 2 through 6 of the classification worksheet, for every row with an amount listed, add the expected claim dollar amounts from Column 1 of the worksheet for the benefit listed in that row.

(2) To determine whether the level of a financial requirement or quantitative treatment limitation applied to MH/SUD is not less favorable than the predominant financial requirement or quantitative treatment limitation applied to medical/surgical benefits, follow the instructions in the following subparagraphs for each financial requirement and quantitative treatment limitation identified in Columns 2 through 4 of each classification worksheet.

(A) Rank each level of each type of financial requirement and quantitative treatment limitation from highest to lowest.

(B) For each level of each type of financial requirement and quantitative treatment limitation identified in Columns 2 through 4 of the classification worksheet, add the expected plan payments identified in Column 1 of the worksheet for each benefit to which the level of financial requirement or quantitative treatment limitation applies.

(C) Divide each amount calculated under subsection (c)(2)(B) of this section by the aggregate total addressed in subsection (c)(1) of this section.

(D) Add the amounts calculated under subsection (c)(2)(C) of this section for each level of each type of financial requirement and quantitative treatment limitation identified in Columns 2 through 4 of the classification worksheet, from highest to lowest, until the aggregate total exceeds 50%.

(E) In each of the classification worksheets, the least restrictive level of each type of financial requirement or quantitative treatment limitation calculated under subsection (c)(2)(D) of this section to exceed 50% is the predominant level and the least restrictive level that can be applied to MH/SUD benefits. For example:

(i) for copays, coinsurance, and deductibles, the predominant level is the highest amount that can be applied to MH/SUD benefits; and

(ii) for day limits and session limits, the predominant level is the lowest level of day or session limits that can be applied to MH/SUD benefits.

§21.2441. Four-Step Analysis of Nonquantitative Treatment Limitations.

(a) Four-step analysis. An issuer must complete the four-step analysis detailed in this section for each NQTL contained in the plan documents for each plan. An issuer must report its NQTL analyses separately for each applicable classification or subclassification, using the classification worksheets as described in subsection (b) of this section.

(b) Step 1. Within the NQTL template, in the worksheet titled "NQTL Summary," an issuer must identify each NQTL that applies to MH/SUD or medical/surgical benefits covered by the plan, including, but not limited to, those identified in §21.2439 of this title (relating to Nonquantitative Treatment Limitations Generally).

(1) Within the NQTL Summary worksheet, an issuer must identify, for each NQTL listed:

(A) whether the NQTL does or does not apply to benefits categorized as:

(i) medical/surgical benefits; and

(ii) MH/SUD benefits; and

(B) whether the NQTL does or does not apply to the following classifications and subclassifications:

(i) in-network inpatient;

(ii) out-of-network inpatient;

(iii) in-network outpatient, including, if applicable:

(I) in-network outpatient - office; and

(II) in-network outpatient - all other;

(iv) out-of-network outpatient, including, if applicable:

(I) out-of-network outpatient - office; and

(II) out-of-network outpatient - all other;

(v) emergency care; or

(vi) prescription drugs.

(2) Within the NQTL template, in each classification or subclassification worksheet, an issuer must provide the specific plan document terms, coverage terms, or other relevant terms regarding the NQTL.

(3) Within the NQTL template, in each classification or subclassification worksheet, an issuer must list all MH/SUD and medical/surgical covered benefits to which each NQTL applies, and:

(A) assign covered benefits to classifications using a comparable methodology across medical/surgical benefits and MH/SUD benefits;

(B) use the same categorization and classification of a given covered benefit for both its QTL and NQTL analyses;

(C) analyze the NQTLs separately for MH/SUD and medical/surgical benefits;

(D) analyze each NQTL separately if a covered benefit includes multiple components (such as outpatient and prescription drug classifications), and each component is subject to a different type of NQTL (such as prior authorization and limits on treatment dosage or duration); and

(E) describe how the requirements for each NQTL are implemented, who makes the decisions, and what the decision maker's qualifications are.

(c) Step 2. Within the NQTL template, in each classification or subclassification worksheet, an issuer must identify each factor considered in the design and application of the NQTL. Illustrative examples of factors are provided in the NQTL template.

(1) If only certain benefits are subject to an NQTL (such as meeting a fail-first protocol or requiring preauthorization), issuers must have information available to substantiate how the applicable factors were used to apply the specific NQTL to medical/surgical and MH/SUD benefits.

(2) An issuer must document whether any factors were given more weight than others and the reasons for doing so, including evaluating the specific data used in the determination (if any).

(d) Step 3. Within the NQTL template, in each classification or subclassification worksheet, an issuer must identify the sources (including any processes, strategies, or evidentiary standards) used to define the factors identified in Step 2 to design and apply the NQTL. Illustrative examples of sources of factors are provided in the NQTL template.

(1) If an issuer uses these sources of factors, they must apply them comparably to MH/SUD and medical/surgical benefits.

(2) Evidentiary standards and processes that an issuer relies on may include any evidence that the issuer considers in developing its medical management techniques, including recognized medical literature and professional standards and protocols (such as comparative effectiveness studies and clinical trials), and published research studies.

(3) If there is any variation in the application of a guideline or standard being relied on by the issuer, an issuer must explain the process and factors relied on for establishing that variation.

(4) If an issuer relies on any experts, the issuer must describe the experts' qualifications and whether the expert evaluations in

setting recommendations for both MH/SUD and medical/surgical conditions are comparable.

(5) When identifying the sources of the factors considered in designing the NQTL, an issuer must identify any threshold at which each factor will implicate the NQTL. For example, if high cost is identified as a factor used in designing a prior authorization requirement, the issuer would identify and explain:

(A) the threshold dollar amount at which prior authorization will be required for any benefit;

(B) the data used to determine the benefit is "high cost"; and

(C) how, if at all, the amount that is to be considered "high cost" is different for MH/SUD benefit as compared with medical/surgical benefits, and how the issuer justifies this difference.

(6) The NQTL template includes examples of how factors identified based on evidentiary standards may be defined to set applicable thresholds for NQTLs.

(e) Step 4. Within the NQTL template, in each classification or subclassification worksheet, an issuer must provide a comparative analysis demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTL to MH/SUD benefits, as written and in operation, are comparable to and are applied no more stringently than the processes, strategies, evidentiary standards, and other factors used to apply the NQTL to medical/surgical benefits. Examples of methods and analyses an issuer could use to substantiate that factors, evidentiary standards, and processes are comparable are included in the NQTL template. When applicable, the comparability analysis must:

(1) demonstrate any methods, analyses, or other evidence used to determine that any factor used, evidentiary standard relied upon, and process employed in developing and applying the NQTL are comparable and applied no more stringently to MH/SUD benefits and medical/surgical benefits;

(2) if utilization review is conducted by different entities or individuals for medical/surgical and MH/SUD benefits, identify the measures in place to ensure comparable application of utilization review policies to the NQTL;

(3) identify any consequences or penalties that apply to the benefits when the NQTL requirement is not met, such as a reduction in benefits if not preauthorized; and

(4) demonstrate compliance both as written and in operation by:

(A) identifying all exception processes available and when they may be applied;

(B) identifying how much discretion is allowed in applying the NQTL and whether such discretion is afforded comparably for processing MH/SUD benefit claims and medical/surgical benefits claims;

(C) identifying who makes denial determinations and whether the decision makers have comparable expertise with respect to MH/SUD and medical/surgical benefits;

(D) performing and documenting an audit to check sample claims to assess how several NQTLs operate in practice, and whether written processes are correctly carried out;

(E) determining and documenting average denial rates and appeal overturn rates for concurrent review, and assessing the par-

ity between these rates for MH/SUD benefits and medical/surgical benefits; and

(F) demonstrating that there are not arbitrary or discriminatory differences in how the issuer applies underlying processes and strategies to NQTLs with respect to medical/surgical benefits versus MH/SUD benefits.

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

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James Person

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Texas Department of Insurance

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For further information, please call: (512) 676-6584



DIVISION 4. AUTISM SPECTRUM DISORDER

28 TAC §21.2451, §21.2452

STATUTORY AUTHORITY. The Commissioner adopts §21.2451 and §21.2452 under Insurance Code §§1355.257, 1355.258, and 36.001.

Insurance Code §1355.257 provides that Chapter 1355, Subchapter F, supplements Subchapters A and B of that chapter, and Chapter 1368, and the rules adopted under those statutes. Insurance Code §1355.257 also provides that the legislature intends that Insurance Code Chapter 1355's Subchapter A or B, Chapter 1368, or a department rule adopted under those statutes, control over Subchapter F in any circumstance in which those statutes or rules require a benefit that is not required by Subchapter F, or require a more extensive benefit than is required by Subchapter F.

Insurance Code §1355.258, addressing coverage for mental health conditions and substance use disorders, requires that the Commissioner adopt rules necessary to implement Chapter 1355, Subchapter F.

Insurance Code §36.001 provides that the Commissioner may adopt any rules necessary and appropriate to implement the powers and duties of TDI under the Insurance Code and other laws of this state.

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

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SUBCHAPTER JJ. AUTISM SPECTRUM DISORDER COVERAGE

28 TAC §§21.4401 - 21.4404

STATUTORY AUTHORITY. The Commissioner adopts the repeal of 28 TAC Subchapter JJ, §§21.4401 - 21.4404, under Insurance Code §§1355.257, 1355.258, and 36.001.

Insurance Code §1355.257 provides that Chapter 1355, Subchapter F, supplements Subchapters A and B of that chapter, and Chapter 1368, and the rules adopted under those statutes. Insurance Code §1355.257 also provides that the legislature intends that Insurance Code Chapter 1355's Subchapter A or B, Chapter 1368, or a department rule adopted under those statutes, control over Subchapter F in any circumstance in which those statutes or rules require a benefit that is not required by Subchapter F, or require a more extensive benefit than is required by Subchapter F.

Insurance Code §1355.258 states that the Commissioner may adopt rules necessary to implement Chapter 1355, Subchapter F.

Insurance Code §36.001 provides that the Commissioner may adopt any rules necessary and appropriate to implement the powers and duties of TDI under the Insurance Code and other laws of this state.

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

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TITLE 40. SOCIAL SERVICES AND ASSISTANCE

PART 19. DEPARTMENT OF FAMILY AND PROTECTIVE SERVICES

CHAPTER 700. CHILD PROTECTIVE SERVICES

SUBCHAPTER A. ADMINISTRATION

40 TAC §700.104, §700.106

The Department of Family and Protective Services (DFPS) adopts the repeal of §700.104 and §700.106 in Title 40, Texas Administrative Code (TAC), Chapter 700, Subchapter A, relating to Administration. The repeals are adopted without changes to the proposed text published in the June 18, 2021 issue of the *Texas Register* (46 TexReg 3723). These repeals will not be republished.

BACKGROUND AND JUSTIFICATION

The justification of the repeals is to consolidate the rules regarding DFPS records and the central registry into one chapter, as currently both Chapters 700 and 702 address records and the central registry.

COMMENTS

The 30-day comment period ended July 18, 2021. During this period, DFPS did not receive any comments regarding the repealed rules.

STATUTORY AUTHORITY

The repealed sections are adopted under Human Resources Code (HRC) §40.027, which provides that the Department of Family and Protective Services commissioner shall oversee the development of rules relating to the matters within the department's jurisdiction and adopt rules for the operation and provision of services by the department.

The adopted repealed sections implement Texas Family Code §261.002 and Texas Government Code §§441.183 - 441.189.

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

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CHAPTER 702. GENERAL ADMINISTRATION

The Department of Family and Protective Services (DFPS) adopts amendments to §§702.201, 702.213, 702.221, 702.251, 702.255, and 702.257; new §§702.203, 702.205, 702.207, 702.209; and the repeals of §§702.205, 702.209, 702.217, 702.223 and 702.253 in Title 40, Texas Administrative Code (TAC), Chapter 702, relating to General Administration. Sections 702.205 and 702.213 are adopted with non-substantive changes to correct grammatical errors in the proposed text as published in the June 18, 2021, issue of the *Texas Register* (46 TexReg 3726), and will be republished. Sections 702.201, 702.203, 702.207, 702.209, 702.213, 702.221, 702.251, 702.255, and 702.257, as well as the repeals of §§702.205, 702.209, 702.217, 702.223 and 702.253, are adopted without changes to the proposed text as published in the June 18, 2021, issue of the *Texas Register* (46 TexReg 3726) and will not be republished.

BACKGROUND AND JUSTIFICATION

The justification of the proposed changes is to update the rules concerning DFPS records to reflect DFPS's current policy and practice of creating and maintaining records, including the central registry, as many of the rules are outdated. These amendments include updates to rule sections concerning what DFPS considers confidential case records, how long DFPS retains records and the process for retaining records, and how an individual can access confidential case records and public records. Finally, the rule changes also include clarifying for the

public and DFPS staff when DFPS will maintain records past the retention schedule pursuant to the mandates in Government Code §441.186, including for litigation holds, and how DFPS uses and handles such records. While the changes appear far reaching, they do not result in any changes to the DFPS records retention schedules, do not increase the amount of time DFPS maintains records, do not change the persons and entities DFPS currently releases records to pursuant to state and federal law, and do not change the process for requesting or releasing records.

COMMENTS

The 30-day comment period ended July 18, 2021. During this period, DFPS did not receive any comments regarding the repealed rules.

SUBCHAPTER B. AGENCY RECORDS AND INFORMATION

40 TAC §§702.201, 702.203, 702.205, 702.207, 702.209, 702.213, 702.221

STATUTORY AUTHORITY

The new and amended sections are adopted under Human Resources Code (HRC) §40.027, which provides that the Department of Family and Protective Services commissioner shall oversee the development of rules relating to the matters within the department's jurisdiction and adopt rules for the operation and provision of services by the department.

The adopted new and amended sections implement Texas Family Code §261.002 and Texas Government Code §§441.183-441.189.

§702.205. How long does the Department of Family and Protective Services retain confidential case records?

(a) Physical case records and case records and information in DFPS's electronic case management system entitled Information Management Protecting Adults and Children in Texas (IMPACT) and other electronic systems are generally retained and destroyed in accordance with the Department of Family and Protective Services' (DFPS) Records Retention Schedule. The Schedule can be found on DFPS's public website. The retention period of a record is calculated from the time the case is closed. When the retention period has expired, DFPS permanently removes the case information from any electronic storage, including IMPACT, and destroys any paper case record in a manner that protects confidentiality.

(b) Notwithstanding subsection (a) of this section, the retention period for a DFPS record may be extended for the following reasons:

(1) Pursuant to Texas Government Code §441.187, if a litigation, claim, negotiation, audit, open records request, administrative review, or other action involving the record is initiated before the retention period for the record expires, DFPS may not destroy the record until the completion of the action and resolution of all issues that arise from the action, even if the retention period for the record expires during that period. If an action or activity involving the record is initiated, the retention period for that record is extended for the amount of time that the action or activity is in process.

(2) If DFPS opens a new case on a party to an older closed case that has not been destroyed pursuant to DFPS's retention schedule, DFPS may merge or relate the cases. Merged cases may be reclassified and extended to coincide with the retention period of the case with

the latest retention period. For purposes of this section, merge means combining two or more separate cases into one case.

(c) If the retention period for a case record is extended as provided in subsection (b) of this section, DFPS may use the information in the case record as necessary to make case related decisions, assess risk of abuse or neglect, or for any other purpose for as long as DFPS retains the case record.

§702.213. How can a member of the public obtain information or copies of administrative records that are not on the Department of Family and Protective Services web site?

Requests for copies of administrative records as defined in §702.201(a) in this subchapter (relating to What types of records are maintained by the Department of Family and Protective Services?) must be submitted following the instructions on the DFPS public website, Open Records Policy. A written request may also be hand delivered to the DFPS headquarters office or mailed to the mailing address found on the DFPS public website.

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

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For further information, please call: (512) 438-3083



40 TAC §§702.205, 702.209, 702.217, 702.223

The repeals are adopted under Human Resources Code (HRC) §40.027, which provides that the Department of Family and Protective Services commissioner shall oversee the development of rules relating to the matters within the department's jurisdiction and adopt rules for the operation and provision of services by the department.

The repeals implement Texas Family Code §261.002 and Texas Government Code §§441.183-441.189.

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

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Vicki Kozikoujekian

General Counsel

Department of Family and Protective Services

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SUBCHAPTER C. CHILD ABUSE AND NEGLECT CENTRAL REGISTRY

40 TAC §§702.251, 702.255, 702.257

The amended sections are adopted under Human Resources Code (HRC) §40.027, which provides that the Department of Family and Protective Services commissioner shall oversee the development of rules relating to the matters within the department's jurisdiction and adopt rules for the operation and provision of services by the department.

The amended sections implement Texas Family Code §261.002 and Texas Government Code §§441.183-441.189.

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40 TAC §702.253

The repeal is adopted under Human Resources Code (HRC) §40.027, which provides that the Department of Family and Protective Services commissioner shall oversee the development of rules relating to the matters within the department's jurisdiction and adopt rules for the operation and provision of services by the department.

The repeal implements Texas Family Code §261.002 and Texas Government Code §§441.183-441.189.

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