Proposed rules include new rules, amendments to existing rules, and repeals of existing rules. A state agency shall give at least 30 days' notice of its intention to adopt a rule before it adopts the rule. A state agency shall give all interested persons a reasonable opportunity to submit data, views, or arguments, orally or in writing (Government Code, Chapter 2001).

Symbols in proposed rule text. Proposed new language is indicated by underlined text. [~~Square brackets and strikethrough~~] indicate existing rule text that is proposed for deletion. "(No change)" indicates that existing rule text at this level will not be amended.

TITLE 1. ADMINISTRATION

PART 12. COMMISSION ON STATE EMERGENCY COMMUNICATIONS

CHAPTER 251. 9-1-1 SERVICE--STANDARDS

1 TAC §251.12

The Commission on State Emergency Communications (CSEC) proposes amendments to 1 TAC §251.12, concerning contracts for 9-1-1 service with a Regional Planning Commission (RPC).

BACKGROUND AND PURPOSE

CSEC proposes amendments to §251.12 (Title 1, Part 12, Chapter 251 of the Texas Administrative Code) relating to contracts for 9-1-1 service with an RPC. The primary purpose of the amendments is to align the rule with CSEC Program Policy Statements (PPS), including with respect to PPS Regional Planning Commission Advance Quarterly Funding the permitted uses of such funding.

SECTION-BY-SECTION EXPLANATION

Section 251.12(a) is amended to change the reference to RPCs from plural to singular; and to change the term "provisioning" to "provide."

Section 251.12(b) is amended to change "contracts" to "a contract"--a complementary change to the change of RPCs from plural to singular.

Section 251.12(b)(1) is amended to delete the redundant reference to "by RPCs."

Section 251.12(b)(2) is amended to reflect the change to singular RPC and add "9-1-1" to clarify the subject service area. change "contracts" to "a contract"--a complementary change from the plural to singular change for RPC.

Section 251.12(b)(4) is amended to specify answering points refers to "public safety" answering points.

Section 251.12(b)(6) - (7) are amended to make a grammatical change from "a" to "an" RPC.

Section 251.12(c) is amended to reference the name of the PPS.

Section 251.12(d) is amended to reference the name of the PPS. Subsection (d) is also amended to replace "start-up" with "advance;" to specify that advance funding is provided at the beginning of each fiscal quarter (not just at the beginning of each year); and specify and limit the use of advance funding to funding operating costs attributable to 9-1-1 service.

FISCAL NOTE

Kelli Merriweather, CSEC's executive director, has determined that for each year of the first five fiscal years (FY) that amended §251.12 is in effect there will be no cost implications to the state or local governments as a result of enforcing or administering the amended sections.

PUBLIC BENEFITS AND COSTS

Ms. Merriweather has determined that for each year of the first five years the amended section is in effect, the public benefits anticipated as a result of the proposed revision will be to ensure the CSEC - RPC contracts for 9-1-1 service align with CSEC PPS; and provide clarity on payment and use of advance quarterly funding.

RULE INCREASING COSTS TO REGULATED PERSONS

Government Code §2001.0045 precludes a state agency from adopting a proposed rule if the fiscal note imposes a cost on regulated persons, including another state agency, a special district, or a local government, unless on or before the effective date the state agency: (a) repeals a rule that imposes a total cost on regulated persons that is equal to or greater than the total cost imposed on regulated persons by the proposed rule; or (b) amends a rule to decrease the total cost imposed on regulated persons by an amount that is equal to or greater than the cost imposed on the persons by the rule. There are exceptions for certain types of rules under §2001.0045(c).

Section 2001.0045(b) is not applicable as no costs are imposed on regulated persons as a result of the amendments. Accordingly, no repeal or amendment of another rule to offset costs is required.

LOCAL EMPLOYMENT IMPACT STATEMENT

CSEC has determined that this proposal does not directly affect a local economy and therefore has not drafted a local employment impact statement as would otherwise be required under Administrative Procedures Act §2001.022.

GOVERNMENT GROWTH IMPACT STATEMENT

In compliance with the requirements of Texas Government Code §2001.0221, CSEC has determined that during the first five years that the rule will be in effect it would: 1. neither create nor eliminate a government program; 2. not result in an increase or decrease in the number of full-time equivalent employee needs; 3. not result in an increase or decrease in future legislative appropriations to the agency; 4. not increase or decrease any fees paid to the agency; 5. not create a new regulation; 6. not expand, limit, or repeal an existing regulation; 7. neither increase or decrease the number of individuals subject to regulation; and 8. not positively or adversely affect Texas' economy.

REGULATORY ANALYSIS OF MAJOR ENVIRONMENTAL RULES

CSEC has determined that this proposal is not a "major environmental rule" as defined by Government Code §2001.0225.

SMALL, MICRO-BUSINESS, AND RURAL COMMUNITY IMPACT ANALYSIS

In accordance with Government Code §2006.002(c), Ms. Merriweather has determined that there will be no adverse economic effect on small businesses, micro-businesses, or rural communities as the rule being proposed affects only the relationship between CSEC and its RPC grantee stakeholders. Accordingly, CSEC has not prepared an economic impact statement or regulatory flexibility analysis, nor has it contacted legislators in any rural communities regarding this proposal.

TAKINGS IMPACT ASSESSMENT

CSEC has determined that the proposal does not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, does not constitute a taking under Government Code §2007.043.

PUBLIC COMMENT

Comments on the proposal may be submitted in writing c/o Patrick Tyler, Commission on State Emergency Communications, 333 Guadalupe Street, Suite 2-212, Austin, Texas 78701-3942, by facsimile to (512) 305-6937, or by email to patrick.tyler@csec.texas.gov. Please include "Rulemaking Comments" in the subject line of your letter, fax, or email. Comments will be accepted for 30 days following publication of the proposal in the *Texas Register.*

STATEMENT OF AUTHORITY

The amended section is proposed pursuant to Health and Safety Code §§771.051, 771.0511, 771.055 - .057, and 771.078.

No other statute, article, or code is affected by the proposal.

§251.12. Commission and Regional Planning Commission Contracts for 9-1-1 Service.

(a) Purpose. The purpose of this rule is to implement the requirement in Health and Safety Code §771.078 that the Commission adopt by rule the standard provisions for a contract [~~contracts~~] between the Commission and a Regional Planning Commission (RPC) to provide 9-1-1 service [~~Commissions (RPCs) for the provisioning of 9-1-1 service~~].

(b) Per Health and Safety Code §771.078(c), a contract [~~contracts~~] under this section must provide for:

(1) the reporting of financial information regarding administrative expenses [~~by RPCs~~] in accordance with generally accepted accounting principles;

(2) the reporting of information regarding the current performance, efficiency, and degree of implementation of emergency communications services in an [~~each~~] RPC's 9-1-1 service area;

(3) the collection of efficiency data on the operation of 9-1-1 answering points;

(4) standards for the use of [~~answering points~~] and the creation of new public safety answering points;

(5) quarterly disbursements of money due under the contract, except as provided by paragraph (6) of this subsection;

(6) the Commission to withhold disbursement to an [~~a~~] RPC that does not follow a standard imposed by the contract, a Commission rule, or a statute; and

(7) a means for the Commission to give an advance on a quarterly distribution under the contract to an [~~a~~] RPC that has a financial emergency.

(c) Per [~~a~~] Commission Program Policy Statement (PPS) Contracts for 9-1-1 Service, the Commission provides a standard form for contracts under this section.

(d) Per [~~a~~] Commission PPS Regional Planning Commission Advance Quarterly Funding, the Commission provides advance [~~start-up~~] funding to an [~~each~~] RPC at the beginning of each fiscal quarter [~~year~~] to fund operating costs attributable to providing 9-1-1 service [~~avoid financial emergencies resulting from a lack of money to pay initial program expenses~~].

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

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

TRD-202101124
Patrick Tyler
General Counsel
Commission on State Emergency Communications
Earliest possible date of adoption: May 2, 2021
For further information, please call: (512) 305-6915

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PART 15. TEXAS HEALTH AND HUMAN SERVICES COMMISSION

CHAPTER 353. MEDICAID MANAGED CARE

The Executive Commissioner of the Texas Health and Human Services Commission (HHSC) proposes amendments to §353.2, concerning Definitions; §353.702, concerning Member Participation; and §353.1203, concerning Member Participation.

BACKGROUND AND PURPOSE

The proposed amendments are in response to Texas Government Code §533.00531, concerning Medicaid benefits for certain children formerly in foster care, which was added by House Bill (H.B.) 72, 86th Legislature, Regular Session, 2019. Section 533.00531 requires HHSC to allow the adoptive parent or permanent managing conservator of a child who participates in the Adoption Assistance (AA) Program or Permanency Care Assistance (PCA) Program operated by the Texas Department of Family and Protective Services, and is receiving Supplemental Security Income (SSI) or was receiving SSI before enrolling in the AA program or PCA program, to choose for the child to receive Medicaid benefits through the STAR Health program or the STAR Kids program, instead of being required to receive benefits through STAR Kids.

The proposed amendments make changes to the eligibility criteria for the STAR Health and STAR Kids programs to implement the requirements of §533.00531. In addition, the proposed amendments allow children and young adults who participate in the AA Program or PCA Program and are enrolled in a Medicaid 1915(c) waiver or Medicare, to choose to receive benefits through the STAR Health program or the STAR Kids program,

unless they are in a category that is specifically excluded from the STAR Kids program.

SECTION-BY-SECTION SUMMARY

The proposed amendment to §353.2 adds definitions of "Adoption Assistance Program" and "Permanency Care Assistance Program" because these terms are used in the proposed amendments to §353.702 and §353.1203. The proposed amendment also adds a definition of "DFPS." The agency is referenced in the new definitions of "Adoption Assistance Program" and "Permanency Care Assistance Program;" in the current definitions of "Former Foster Care Children Program," "Medicaid for transitioning foster care youth program," and "STAR Health;" and in §353.702(a)(1) and §353.1203(d)(5). The acronym improves the readability of those provisions.

The proposed amendment to §353.702 adds certain children and young adults, from birth through the month of their 21st birthday, who are enrolled in the AA program or the PCA program to the categories of persons eligible for the STAR Health program. Specifically, the proposed amendment makes such a child or young adult eligible for the STAR Health program if the child or young adult is receiving SSI; was receiving SSI before becoming eligible for the AA program or the PCA program; is enrolled in a Medicaid 1915(c) waiver; or is enrolled in Medicare. Subsection (c)(5), which currently excludes children and youth who are receiving Medicaid benefits through the AA program from the STAR Health program, has been deleted because the proposed amendment to this section makes some of those children and young adults eligible for STAR Health. The proposed amendment also makes minor changes to subsection (a)(2) and (3) to clarify the age ranges of children and young adults who are eligible for the STAR Health program. The proposed amendment changes "and" to "or" in subsection (b) to clarify that a young adult must only be described in subsection (a)(2) or (3), not both, to be able to choose to transfer from the STAR Health program to the STAR program or STAR Kids program.

The proposed amendment to §353.1203 adds the same categories of children and young adults to the eligibility categories for STAR Kids as the categories being added to §353.702 for STAR Health in new subsection (i). Subsection (h), which currently requires children and youth who are receiving Medicaid benefits through the AA program or the PCA program to enroll in STAR Kids if they meet the criteria described in subsections (a), (b), (c), or (e), has been deleted because the proposed new subsection (i) allows these children and young adults to have a choice of receiving benefits from the STAR Kids program or the STAR Health program. In addition, the proposed amendment changes the term "STAR Kids Medicaid client" to "STAR Kids member" in re-lettered subsection (h) because "member" refers to a person who is enrolled in a managed care program, which is appropriate in this context. The proposed amendment also makes minor changes to subsections (a), (b), (c), (f), and (g) to clarify the age ranges of children and young adults who are eligible for the STAR Kids program.

FISCAL NOTE

Trey Wood, HHSC Chief Financial Officer, has determined that for each year of the first five years that the rules will be in effect, there will be an estimated additional cost to the state as a result of enforcing and administering the rules as proposed. Enforcing or administering the rules does not have foreseeable implications relating to costs or revenues of local government.

The effect on state government for each year of the first five years the proposed rules are in effect is an estimated net cost of $678,981 General Revenue (GR) ($747,535 Federal Funds (FF), $1,426,516 All Funds (AF)) for State Fiscal Year (SFY) 2021 and estimated net savings of $272,278 GR ($458,638 FF, $730,916 AF) for SFY 2022; $276,855 GR ($471,306 FF, $748,161 AF) for SFY 2023, $291,143 GR ($486,330 FF, $777,473 AF) for SFY 2024; and $300,391 GR ($501,835 FF, $802,226 AF) for SFY 2025.

GOVERNMENT GROWTH IMPACT STATEMENT

HHSC has determined that during the first five years that the rules will be in effect:

(1) the proposed rules will not create or eliminate a government program;

(2) implementation of the proposed rules will not affect the number of HHSC employee positions;

(3) implementation of the proposed rules will require an increase in future legislative appropriations;

(4) the proposed rules will not affect fees paid to HHSC;

(5) the proposed rules will not create new rules;

(6) the proposed rules will not expand existing rules; and

(7) the proposed rules will not change the number of individuals subject to the rules.

(8) the proposed rules will not affect the state's economy.

SMALL BUSINESS, MICRO-BUSINESS, AND RURAL COMMUNITY IMPACT ANALYSIS

Trey Wood has also determined that there will be no adverse economic effect on small businesses, micro-businesses, or rural communities. The rules do not impose any additional costs on small businesses, micro businesses, or rural communities that are required to comply with the rules.

LOCAL EMPLOYMENT IMPACT

The proposed rules will not affect a local economy.

COSTS TO REGULATED PERSONS

Texas Government Code §2001.0045 does not apply to these rules because the rules do not impose a cost on regulated persons.

PUBLIC BENEFIT AND COSTS

Stephanie Stephens, State Medicaid Director, has determined that for each year of the first five years the rules are in effect, the public benefit will be improved continuity of care for children and young adults formerly in foster care by allowing them to obtain services more efficiently.

Trey Wood has also determined that for the first five years the rules are in effect, there are no anticipated economic costs to persons who are required to comply with the proposed rules because the proposed amendments do not impose any new costs or fees on those required to comply.

TAKINGS IMPACT ASSESSMENT

HHSC has determined that the proposal does not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, does not constitute a taking under Texas Government Code §2007.043.

PUBLIC COMMENT

Written comments on the proposal may be submitted to Rules Coordination Office, P.O. Box 13247, Mail Code 4102, Austin, Texas 78711-3247, or street address 4900 North Lamar Boulevard, Austin, Texas 78751; or emailed to HHSRulesCoordinationOffice@hhs.texas.gov.

To be considered, comments must be submitted no later than 31 days after the date of this issue of the *Texas Register.* Comments must be: (1) postmarked or shipped before the last day of the comment period; (2) hand-delivered before 5:00 p.m. on the last working day of the comment period; or (3) emailed before midnight on the last day of the comment period. If the last day to submit comments falls on a holiday comments must be postmarked, shipped, or emailed before midnight on the following business day to be accepted. When emailing comments, please indicate "Comments on Proposed Rule 20R037" in the subject line.

SUBCHAPTER A. GENERAL PROVISIONS

1 TAC §353.2

STATUTORY AUTHORITY

The amendments are authorized by Texas Government Code §531.00531, which requires the Executive Commissioner to adopt rules necessary to implement requirements relating to Medicaid benefits for certain children formerly in foster care; §531.0055, which requires the Executive Commissioner of HHSC to adopt rules for the operation and provision of services by the health and human services agencies; §531.021(a), which authorizes HHSC to administer the federal medical assistance (Medicaid) program; §531.033, which directs the Executive Commissioner of HHSC to adopt rules as necessary to carry out the commission's duties; and Texas Human Resources Code §32.021(c), which requires the Executive Commissioner of HHSC to adopt necessary rules for the proper and efficient operation of the Medicaid program.

The amendments affect Texas Government Code §§531.021, 531.033, 531.0055, and 531.00531; and Texas Human Resources Code §32.021.

§§353.2. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise.

(1) Action--

(A) An action is defined as:

(i) the denial or limited authorization of a requested Medicaid service, including the type or level of service;

(ii) the reduction, suspension, or termination of a previously authorized service;

(iii) the failure to provide services in a timely manner;

(iv) the denial in whole or in part of payment for a service; or

(v) the failure of a managed care organization (MCO) to act within the timeframes set forth by the Texas Health and Human Services Commission (HHSC) and state and federal law.

(B) "Action" does not include expiration of a time-limited service.

(2) Acute care--Preventive care, primary care, and other medical or behavioral health care provided by the provider or under the direction of a provider for a condition having a relatively short duration.

(3) Acute care hospital--A hospital that provides acute care services.

(4) Adoption Assistance Program--The program administered by DFPS in accordance with 40 TAC Chapter 700, Subchapter H (relating to Adoption Assistance Program).

(5) [~~(4)~~] Agreement or Contract--The formal, written, and legally enforceable contract and amendments thereto between HHSC and an MCO.

(6) [~~(5)~~] Allowable revenue--All managed care revenue received by the MCO pursuant to the contract during the contract period, including retroactive adjustments made by HHSC. This would include any revenue earned on Medicaid managed care funds such as investment income, earned interest, or third party administrator earnings from services to delegated networks.

(7) [~~(6)~~] Appeal--The formal process by which a member or his or her representative requests a review of the MCO's action.

(8) [~~(7)~~] Applicant Provider--A physician or other health care provider applying for expedited credentialing as defined in Texas Government Code §533.0064.

(9) [~~(8)~~] Behavioral health service--A covered service for the treatment of mental, emotional, or substance use disorders.

(10) [~~(9)~~] Capitated service--A benefit available to members under the Texas Medicaid program for which an MCO is responsible for payment.

(11) [~~(10)~~] Capitation rate--A fixed predetermined fee paid by HHSC to the MCO each month, in accordance with the contract, for each enrolled member in exchange for which the MCO arranges for or provides a defined set of covered services to the member, regardless of the amount of covered services used by the enrolled member.

(12) [~~(11)~~] CFR--Code of Federal Regulations.

(13) [~~(12)~~] Children's Medicaid Dental Services--The dental services provided through a dental MCO to a client birth through age 20.

(14) [~~(13)~~] Clean claim--A claim submitted by a physician or provider for health care services rendered to a member, with the data necessary for the MCO or subcontracted claims processor to adjudicate and accurately report the claim. A clean claim must meet all requirements for accurate and complete data as further defined under the terms of the contract executed between the MCO and HHSC.

(15) [~~(14)~~] Client--Any Medicaid-eligible recipient.

(16) [~~(15)~~] CMS--The Centers for Medicare & Medicaid Services, which is the federal agency responsible for administering Medicare and overseeing state administration of Medicaid.

(17) [~~(16)~~] Complainant--A member, or a treating provider or other individual designated to act on behalf of the member, who files a complaint.

(18) [~~(17)~~] Complaint--Any dissatisfaction expressed by a complainant, orally or in writing, to the MCO about any matter related to the MCO other than an action. Subjects for complaints may include:

(A) the quality of care of services provided;

(B) aspects of interpersonal relationships such as rudeness of a provider or employee; and

(C) failure to respect the member's rights.

(19) [~~(18)~~] Consumer Directed Services (CDS) option--A service delivery option (also known as self-directed model with service budget) in which an individual or legally authorized representative employs and retains service providers and directs the delivery of certain program services.

(20) [~~(19)~~] Covered services--Unless a service or item is specifically excluded under the terms of the state plan, a federal waiver, a managed care services contract, or an amendment to any of these, the phrase "covered services" means all health care, long term services and supports, or dental services or items that the MCO must arrange to provide and pay for on a member's behalf under the terms of the contract executed between the MCO and HHSC, including:

(A) all services or items comprising "medical assistance" as defined in §32.003 of the Human Resources Code; and

(B) all value-added services under such contract.

(21) [~~(20)~~] Credentialing--The process through which an MCO collects, assesses, and validates qualifications and other relevant information pertaining to a Medicaid enrolled health care provider to determine whether the provider may be contracted to deliver covered services as part of the network of the managed care organization.

(22) [~~(21)~~] Cultural competency--The ability of individuals and systems to provide services effectively to people of various disabilities, cultures, races, ethnic backgrounds, and religions in a manner that recognizes, values, affirms, and respects the worth of the individuals and protects and preserves their dignity.

(23) [~~(22)~~] Day--A calendar day, unless specified otherwise.

(24) [~~(23)~~] Default enrollment--The process established by HHSC to assign a Medicaid managed care enrollee to an MCO when the enrollee has not selected an MCO.

(25) [~~(24)~~] Dental contractor--A dental MCO that is under contract with HHSC for the delivery of dental services.

(26) [~~(25)~~] Dental home--A provider who has contracted with a dental MCO to serve as a dental home to a member and who is responsible for providing routine preventive, diagnostic, urgent, therapeutic, initial, and primary care to patients, maintaining the continuity of patient care, and initiating referral for care. Provider types that can serve as dental homes are federally qualified health centers and individuals who are general dentists or pediatric dentists.

(27) [~~(26)~~] Dental managed care organization (dental MCO)--A dental indemnity insurance provider or dental health maintenance organization licensed or approved by the Texas Department of Insurance.

(28) [~~(27)~~] Dental service--The routine preventive, diagnostic, urgent, therapeutic, initial, and primary care provided to a member and included within the scope of HHSC's agreement with a dental contractor. For purposes of this chapter, "dental service" does not include dental devices for craniofacial anomalies; treatment rendered in a hospital, urgent care center, or ambulatory surgical center setting for craniofacial anomalies; or emergency services provided in a hospital, urgent care center, or ambulatory surgical center setting involving dental trauma. These types of services are treated as health care services in this chapter.

(29) DFPS--The Texas Department of Family and Protective Services.

(30) [~~(28)~~] Disability--A physical or mental impairment that substantially limits one or more of an individual's major life activities, such as caring for oneself, performing manual tasks, walking, seeing, hearing, speaking, breathing, learning, socializing, or working.

(31) [~~(29)~~] Disproportionate Share Hospital (DSH)--A hospital that serves a higher than average number of Medicaid and other low-income patients and receives additional reimbursement from the State.

(32) [~~(30)~~] Dual eligible--A Medicaid recipient who is also eligible for Medicare.

(33) [~~(31)~~] Elective enrollment--Selection of a primary care provider (PCP) and MCO by a client during the enrollment period established by HHSC.

(34) [~~(32)~~] Emergency behavioral health condition--Any condition, without regard to the nature or cause of the condition, that in the opinion of a prudent layperson possessing an average knowledge of health and medicine:

(A) requires immediate intervention and/or medical attention without which the client would present an immediate danger to themselves or others; or

(B) renders the client incapable of controlling, knowing, or understanding the consequences of his or her actions.

(35) [~~(33)~~] Emergency medical condition--A medical condition manifesting itself by acute symptoms of recent onset and sufficient severity (including severe pain), such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical care to result in:

(A) placing the patient's health in serious jeopardy;

(B) serious impairment to bodily functions;

(C) serious dysfunction of any bodily organ or part;

(D) serious disfigurement; or

(E) serious jeopardy to the health of a pregnant woman or her unborn child.

(36) [~~(34)~~] Emergency service--A covered inpatient and outpatient service, furnished by a network provider or out-of-network provider that is qualified to furnish such service, that is needed to evaluate or stabilize an emergency medical condition and/or an emergency behavioral health condition. For health care MCOs, the term "emergency service" includes post-stabilization care services.

(37) [~~(35)~~] Encounter--A covered service or group of covered services delivered by a provider to a member during a visit between the member and provider. This also includes value-added services.

(38) [~~(36)~~] Enrollment--The process by which an individual determined to be eligible for Medicaid is enrolled in a Medicaid MCO serving the service area in which the individual resides.

(39) [~~(37)~~] EPSDT--The federally mandated Early and Periodic Screening, Diagnosis, and Treatment program defined in 25 TAC Chapter 33 (relating to Early and Periodic Screening, Diagnosis, and Treatment). The State of Texas has adopted the name Texas Health Steps (THSteps) for its EPSDT program.

(40) [~~(38)~~] EPSDT-CCP--The Early and Periodic Screening, Diagnosis, and Treatment-Comprehensive Care Program de-

scribed in Chapter 363 of this title (relating to Texas Health Steps Comprehensive Care Program).

(41) [~~(39)~~] Exclusive provider benefit plan (EPBP)--An MCO that complies with 28 TAC §§3.9201 - 3.9212, relating to the Texas Department of Insurance's requirements for EPBPs, and contracts with HHSC to provide Medicaid coverage.

(42) [~~(40)~~] Expedited Credentialing--The process under Texas Government Code §533.0064 in which an MCO allows an applicant provider to provide Medicaid services to members on a provisional basis pending completion of the credentialing process.

(43) [~~(41)~~] Experience rebate--The portion of the MCO's net income before taxes that is returned to the State in accordance with the MCO's contract with HHSC.

(44) [~~(42)~~] Fair hearing--The process adopted and implemented by HHSC in Chapter 357, Subchapter A of this title (relating to Uniform Fair Hearing Rules) in compliance with federal regulations and state rules relating to Medicaid fair hearings.

(45) [~~(43)~~] Federal Poverty Level (FPL)--The household income guidelines issued annually and published in the *Federal Register* by the United States Department of Health and Human Services under the authority of 42 U.S.C. §9902(2) and as in effect for the applicable budget period determined in accordance with 42 C.F.R. §435.603(h). HHSC uses the FPL to determine an individual's eligibility for Medicaid.

(46) [~~(44)~~] Federal waiver--Any waiver permitted under federal law and approved by CMS that allows states to implement Medicaid managed care.

(47) [~~(45)~~] Federally Qualified Health Center (FQHC)--An entity that is certified by CMS to meet the requirements of 42 U.S.C. §1395x(aa)(3) as a Federally Qualified Health Center and is enrolled as a provider in the Texas Medicaid program.

(48) [~~(46)~~] Former Foster Care Children (FFCC) program--The Medicaid program for young adults who aged out of the conservatorship of DFPS [~~Texas Department of Family and Protective Services (DFPS)~~], administered in accordance with Chapter 366, Subchapter J of this title (relating to Former Foster Care Children's Program).

(49) [~~(47)~~] Functional necessity--A member's need for services and supports with activities of daily living or instrumental activities of daily living to be healthy and safe in the most integrated setting possible. This determination is based on the results of a functional assessment.

(50) [~~(48)~~] Habilitation--Acquisition, maintenance, and enhancement of skills necessary for the individual to accomplish ADLs, IADLs, and health-related tasks based on the individual's person-centered service plan.

(51) [~~(49)~~] Health and Human Services Commission (HHSC)--The single state agency charged with administration and oversight of the Texas Medicaid program or its designee.

(52) [~~(50)~~] Health care managed care organization (health care MCO)--An entity that is licensed or approved by the Texas Department of Insurance to operate as a health maintenance organization or to issue an EPBP.

(53) [~~(51)~~] Health care provider group--A legal entity, such as a partnership, corporation, limited liability company, or professional association, enrolled in Medicaid, under which certified or licensed individual health care providers provide health care items or services.

(54) [~~(52)~~] Health care services--The acute care, behavioral health care, and health-related services that an enrolled population might reasonably require in order to be maintained in good health, including, at a minimum, emergency services and inpatient and outpatient services.

(55) [~~(53)~~] Health maintenance organization (HMO)--An organization that holds a certificate of authority from the Texas Department of Insurance to operate as an HMO under Chapter 843 of the Texas Insurance Code, or a certified Approved Non-Profit Health Corporation formed in compliance with Chapter 844 of the Texas Insurance Code.

(56) [~~(54)~~] Hospital--A licensed public or private institution as defined in the Texas Health and Safety Code at Chapter 241, relating to hospitals, or Chapter 261, relating to municipal hospitals.

(57) [~~(55)~~] Intermediate care facility for individuals with an intellectual disability or related condition (ICF-IID)--A facility providing care and services to individuals with intellectual disabilities or related conditions as defined in §1905(d) of the Social Security Act (42 U.S.C. 1396(d)).

(58) [~~(56)~~] Legally authorized representative (LAR)--A person authorized by law to act on behalf of an individual with regard to a matter described in this chapter, and may, depending on the circumstances, include a parent, guardian, or managing conservator of a minor, or the guardian of an adult, or a representative designated pursuant to 42 C.F.R. 435.923.

(59) [~~(57)~~] Long term service and support (LTSS)--A service provided to a qualified member in his or her home or other community-based setting necessary to allow the member to remain in the most integrated setting possible. LTSS includes services provided under the Texas State Plan as well as services available to persons who qualify for STAR+PLUS Home and Community-Based Program services or Medicaid 1915(c) waiver services. LTSS available through an MCO in STAR+PLUS, STAR Health, and STAR Kids varies by program model.

(60) [~~(58)~~] Main dental home provider--See definition of "dental home" in this section.

(61) [~~(59)~~] Main dentist--See definition of "dental home" in this section.

(62) [~~(60)~~] Managed care--A health care delivery system or dental services delivery system in which the overall care of a patient is coordinated by or through a single provider or organization.

(63) [~~(61)~~] Managed care organization (MCO)--A dental MCO or a health care MCO.

(64) [~~(62)~~] Marketing--Any communication from an MCO to a client who is not enrolled with the MCO that can reasonably be interpreted as intended to influence the client's decision to enroll, not to enroll, or to disenroll from a particular MCO.

(65) [~~(63)~~] Marketing materials--Materials that are produced in any medium by or on behalf of the MCO that can reasonably be interpreted as intending to market to potential members. Materials relating to the prevention, diagnosis, or treatment of a medical or dental condition are not marketing materials.

(66) [~~(64)~~] MDCP--Medically Dependent Children Program. A §1915(c) waiver program that provides community-based services to assist Medicaid beneficiaries under age 21 to live in the community and avoid institutionalization.

(67) [~~(65)~~] Medicaid--The medical assistance program authorized and funded pursuant to Title XIX of the Social Security Act (42 U.S.C. §1396 *et seq.*) and administered by HHSC.

(68) [~~(66)~~] Medicaid for transitioning foster care youth (MTFCY) program--The Medicaid program for young adults who aged out of the conservatorship of DFPS [~~Texas Department of Family and Protective Services (DFPS)~~], administered in accordance with Chapter 366, Subchapter F of this title (relating to Medicaid for Transitioning Foster Care Youth).

(69) [~~(67)~~] Medical Assistance Only (MAO)--A person who qualifies financially and functionally for Medicaid assistance but does not receive Supplemental Security Income (SSI) benefits, as defined in Chapters 358, 360, and 361, of this title (relating to Medicaid Eligibility for the Elderly and People with Disabilities, Medicaid Buy-In Program and Medicaid Buy-In for Children Program).

(70) [~~(68)~~] Medical home--A PCP or specialty care provider who has accepted the responsibility for providing accessible, continuous, comprehensive, and coordinated care to members participating in an MCO contracted with HHSC.

(71) [~~(69)~~] Medically necessary--

(A) For Medicaid members birth through age 20, the following Texas Health Steps services:

(i) screening, vision, dental, and hearing services; and

(ii) other health care services or dental services that are necessary to correct or ameliorate a defect or physical or mental illness or condition. A determination of whether a service is necessary to correct or ameliorate a defect or physical or mental illness or condition:

(I) must comply with the requirements of a final court order that applies to the Texas Medicaid program or the Texas Medicaid managed care program as a whole; and

(II) may include consideration of other relevant factors, such as the criteria described in subparagraphs (B)(ii) - (vii) and (C)(ii) - (vii) of this paragraph.

(B) For Medicaid members over age 20, non-behavioral health services that are:

(i) reasonable and necessary to prevent illnesses or medical conditions, or provide early screening, interventions, or treatments for conditions that cause suffering or pain, cause physical deformity or limitations in function, threaten to cause or worsen a disability, cause illness or infirmity of a member, or endanger life;

(ii) provided at appropriate facilities and at the appropriate levels of care for the treatment of a member's health conditions;

(iii) consistent with health care practice guidelines and standards that are endorsed by professionally recognized health care organizations or governmental agencies;

(iv) consistent with the member's medical need;

(v) no more intrusive or restrictive than necessary to provide a proper balance of safety, effectiveness, and efficiency;

(vi) not experimental or investigative; and

(vii) not primarily for the convenience of the member or provider.

(C) For Medicaid members over age 20, behavioral health services that:

(i) are reasonable and necessary for the diagnosis or treatment of a mental health or substance use disorder, or to improve, maintain, or prevent deterioration of functioning resulting from such a disorder;

(ii) are in accordance with professionally accepted clinical guidelines and standards of practice in behavioral health care;

(iii) are furnished in the most appropriate and least restrictive setting in which services can be safely provided;

(iv) are the most appropriate level or supply of service that can safely be provided;

(v) could not be omitted without adversely affecting the member's mental and/or physical health or the quality of care rendered;

(vi) are not experimental or investigative; and

(vii) are not primarily for the convenience of the member or provider.

(72) [~~(70)~~] Member--A person who is eligible for benefits under Title XIX of the Social Security Act and Medicaid, is in a Medicaid eligibility category included in the Medicaid managed care program, and is enrolled in a Medicaid MCO.

(73) [~~(71)~~] Member education program--A planned program of education:

(A) concerning access to health care services or dental services through the MCO and about specific health or dental topics;

(B) that is approved by HHSC; and

(C) that is provided to members through a variety of mechanisms that must include, at a minimum, written materials and face-to-face or audiovisual communications.

(74) [~~(72)~~] Member materials--All written materials produced or authorized by the MCO and distributed to members or potential members containing information concerning the managed care program. Member materials include member ID cards, member handbooks, provider directories, and marketing materials.

(75) [~~(73)~~] Non-capitated service--A benefit available to members under the Texas Medicaid program for which an MCO is not responsible for payment.

(76) [~~(74)~~] Outside regular business hours--As applied to FQHCs and rural health clinics (RHCs), means before 8 a.m. and after 5 p.m. Monday through Friday, weekends, and federal holidays.

(77) [~~(75)~~] Participating MCO--An MCO that has a contract with HHSC to provide services to members.

(78) Permanency Care Assistance Program--The program administered by DFPS in accordance with 40 TAC Chapter 700, Subchapter J, Division 2 (relating to Permanency Care Assistance Program).

(79) [~~(76)~~] Person-centered care--An approach to care that focuses on members as individuals and supports caregivers working most closely with them. It involves a continual process of listening, testing new approaches, and changing routines and organizational approaches in an effort to individualize and de-institutionalize the care environment.

(80) [~~(77)~~] Person-centered planning--A documented service planning process that includes people chosen by the individual, is directed by the individual to the maximum extent possible, enables the individual to make choices and decisions, is timely and occurs at times

and locations convenient to the individual, reflects cultural considerations of the individual, includes strategies for solving conflict or disagreement within the process, offers choices to the individual regarding the services and supports they receive and from whom, includes a method for the individual to require updates to the plan, and records alternative settings that were considered by the individual.

(81) [~~(78)~~] Post-stabilization care service--A covered service, related to an emergency medical condition, that is provided after a Medicaid member is stabilized in order to maintain the stabilized condition, or, under the circumstances described in 42 C.F.R. §438.114(b) and (e) and 42 C.F.R. §422.113(c)(iii) to improve or resolve the Medicaid member's condition.

(82) [~~(79)~~] Primary care provider (PCP)--A physician or other provider who has agreed with the health care MCO to provide a medical home to members and who is responsible for providing initial and primary care to patients, maintaining the continuity of patient care, and initiating referral for care.

(83) [~~(80)~~] Provider--A credentialed and licensed individual, facility, agency, institution, organization, or other entity, and its employees and subcontractors, that has a contract with the MCO for the delivery of covered services to the MCO's members.

(84) [~~(81)~~] Provider education program--Program of education about the Medicaid managed care program and about specific health or dental care issues presented by the MCO to its providers through written materials and training events.

(85) [~~(82)~~] Provider network or Network--All providers that have contracted with the MCO for the applicable managed care program.

(86) [~~(83)~~] Quality improvement--A system to continuously examine, monitor, and revise processes and systems that support and improve administrative and clinical functions.

(87) [~~(84)~~] Rural Health Clinic (RHC)--An entity that meets all of the requirements for designation as a rural health clinic under §1861(aa)(1) of the Social Security Act (42 U.S.C. §1395x(aa)(1)) and is approved for participation in the Texas Medicaid program.

(88) [~~(85)~~] Service area--The counties included in any HHSC-defined service area as applicable to each MCO.

(89) [~~(86)~~] Significant traditional provider (STP)--A provider identified by HHSC as having provided a significant level of care to the target population, including a DSH.

(90) [~~(87)~~] STAR--The State of Texas Access Reform (STAR) managed care program that operates under a federal waiver and primarily provides, arranges for, and coordinates preventive, primary, acute care, and pharmacy services for low-income families, children, and pregnant women.

(91) [~~(88)~~] STAR Health--The managed care program that operates under the Medicaid state plan and primarily serves:

(A) children and youth in DFPS [~~Texas Department of Family and Protective Services (DFPS)~~] conservatorship;

(B) young adults who voluntarily agree to continue in a foster care placement (if the state as conservator elects to place the child in managed care); and

(C) young adults who are eligible for Medicaid as a result of their former foster care status through the month of their 21st birthday.

(92) [~~(89)~~] STAR Kids--The program that operates under a federal waiver and primarily provides, arranges, and coordinates preventative, primary, acute care, and long-term services and supports to persons with disabilities under the age of 21 who qualify for Medicaid.

(93) [~~(90)~~] STAR+PLUS--The managed care program that operates under a federal waiver and primarily provides, arranges, and coordinates preventive, primary, acute care, and long-term services and supports to persons with disabilities and elderly persons age 65 and over who qualify for Medicaid by virtue of their SSI or MAO status.

(94) [~~(91)~~] STAR+PLUS Home and Community-Based Services Program--The program that provides person-centered care services that are delivered in the home or in a community setting, as authorized through a federal waiver under §1115 of the Social Security Act, to qualified Medicaid-eligible clients who are age 21 or older, as cost-effective alternatives to institutional care in nursing facilities.

(95) [~~(92)~~] State plan--The agreement between the CMS and HHSC regarding the operation of the Texas Medicaid program, in accordance with the requirements of Title XIX of the Social Security Act.

(96) [~~(93)~~] Supplemental Security Income (SSI)--The federal cash assistance program of direct financial payments to people who are 65 years of age or older, are blind, or have a disability administered by the Social Security Administration (SSA) under Title XVI of the Social Security Act. All persons who are certified as eligible for SSI in Texas are eligible for Medicaid. Local SSA claims representatives make SSI eligibility determinations. The transactions are forwarded to the SSA in Baltimore, which then notifies the states through the State Data Exchange (SDX).

(97) [~~(94)~~] Texas Health Steps (THSteps)--The name adopted by the State of Texas for the federally mandated Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) services, described at 42 U.S.C. §1396d(r) and 42 CFR §440.40 and §§441.40 - 441.62.

(98) [~~(95)~~] Value-added service--A service provided by an MCO that is not "medical assistance," as defined by §32.003 of the Texas Human Resources Code.

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

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Karen Ray
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Texas Health and Human Services Commission
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For further information, please call: (512) 438-3360

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SUBCHAPTER H. STAR HEALTH

1 TAC §353.702

STATUTORY AUTHORITY

The amendment is authorized by Texas Government Code §531.00531, which requires the Executive Commissioner to adopt rules necessary to implement requirements relating to Medicaid benefits for certain children formerly in foster care; §531.0055, which requires the Executive Commissioner of HHSC to adopt rules for the operation and provision of services by the health and human services agencies; §531.021(a), which authorizes HHSC to administer the federal medical assistance

(Medicaid) program; §531.033, which directs the Executive Commissioner of HHSC to adopt rules as necessary to carry out the commission's duties; and Texas Human Resources Code §32.021(c), which requires the Executive Commissioner of HHSC to adopt necessary rules for the proper and efficient operation of the Medicaid program.

The amendment affects Texas Government Code §§531.021, 531.033, 531.0055, and 531.00531; and Texas Human Resources Code §32.021.

§353.702. Member Participation.

(a) Children and young adults in the following categories are eligible to participate in the STAR Health program:

(1) a child in the conservatorship of DFPS [~~the Texas Department of Family and Protective Services (DFPS)~~], if the state as conservator elects to place the child in the STAR Health program;

(2) a young adult, from [~~age~~] 18 years of age through the month of his or her 22nd birthday, who voluntarily agrees to continue in foster care placement, if the state as conservator elects to place the child in the STAR Health program; [~~and~~]

(3) a young adult, from [~~age~~] 18 years of age through the month of his or her 21st birthday, who is an FFCC member or participating in the MTFCY Program; and [~~.~~]

(4) a child or young adult, from birth through the month of his or her 21st birthday, who is enrolled in the Adoption Assistance Program or the Permanency Care Assistance Program and who:

(A) receives Social Security Income (SSI);

(B) received SSI before becoming eligible for the Adoption Assistance Program or the Permanency Care Assistance Program;

(C) is enrolled in a Medicaid 1915(c) waiver; or

(D) is enrolled in Medicare.

(b) A young adult described in subsection (a)(2) or [~~and~~] (3) of this section may choose to transfer from the STAR Health program to the STAR program or STAR Kids program, if the young adult meets [~~they meet~~] the member participation requirements in §353.802 of this chapter (relating to Member Participation) or §353.1203 of this chapter (relating to Member Participation).

(c) The following Medicaid recipients cannot participate in the STAR Health program:

(1) Children and youth who have been adjudicated and placed with the Texas Juvenile Justice Department (TJJD);

(2) Children and youth from other states who are placed in Texas through the Interstate Compact Placement Commission (ICPC) as defined by DFPS in 40 TAC Chapter 700, Subchapter S (relating to Interstate Placement of Children);

(3) Children and youth in Medicaid-paid facilities such as nursing facilities or state supported living centers;

(4) Children and youth who are in the conservatorship of DFPS who are placed outside of Texas; and

[~~(5) Children and youth who are receiving adoption assistance Medicaid as defined by DFPS in 40 TAC Chapter 700, Subchapter H (relating to Adoption Assistance Program); and~~]

(5) [~~(6)~~] Children who are declared manifestly dangerous as defined by the Texas Department of Health Services in accordance with 25 TAC Chapter 415, Subchapter G (relating to Determination of Manifest Dangerousness).

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

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Karen Ray
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SUBCHAPTER N. STAR KIDS

1 TAC §353.1203

STATUTORY AUTHORITY

The amendment is authorized by Texas Government Code §531.00531, which requires the Executive Commissioner to adopt rules necessary to implement requirements relating to Medicaid benefits for certain children formerly in foster care; §531.0055, which requires the Executive Commissioner of HHSC to adopt rules for the operation and provision of services by the health and human services agencies; §531.021(a), which authorizes HHSC to administer the federal medical assistance (Medicaid) program; §531.033, which directs the Executive Commissioner of HHSC to adopt rules as necessary to carry out the commission's duties; and Texas Human Resources Code §32.021(c), which requires the Executive Commissioner of HHSC to adopt necessary rules for the proper and efficient operation of the Medicaid program.

The amendment affects Texas Government Code §§531.021, 531.033, 531.0055, and 531.00531; and Texas Human Resources Code §32.021.

§353.1203. Member Participation.

(a) Except as provided in subsection (b) of this section, enrollment in the STAR Kids program is *mandatory* for a Medicaid client who is younger than [~~under the age of~~] 21years of age and meets one or both of the following criteria:

(1) has a physical or mental disability and qualifies for Supplemental Security Income (SSI) or SSI-related Medicaid; or

(2) is enrolled in the Medically Dependent Children Program (MDCP) waiver.

(b) Clients younger than 21 years of age [~~birth through age 20~~] residing in a community-based ICF-IID or nursing facility or receiving services under the following Medicaid 1915(c) waivers must enroll in STAR Kids to receive acute care services and non-facility based state plan services:

(1) Home and Community-based Services (HCS);

(2) Community Living Assistance and Support Services (CLASS);

(3) Texas Home Living (TxHmL); or

(4) Deaf Blind with Multiple Disabilities (DBMD).

(c) Clients younger than 21 years of age [~~birth through age 20~~] receiving services under the Youth Empowerment Services (YES)

Medicaid 1915(c) waiver must enroll in STAR Kids to receive acute care services and non-facility based state plan services other than Community First Choice state plan services.

(d) The following Medicaid clients cannot participate in the STAR Kids program:

(1) clients residing in the Truman W. Smith Children's Care Center;

(2) residents of state supported living centers;

(3) residents of state veterans' homes;

(4) persons not eligible for full Medicaid benefits; and

(5) children in the conservatorship of DFPS [~~the Texas Department of Family and Protective Services~~].

(e) Dual eligible clients.

(1) Enrollment in Medicare does not affect eligibility for the STAR Kids program.

(2) Dual eligible clients who participate in the STAR Kids program receive most acute care services through their Medicare provider, and long term services and supports through the STAR Kids MCO. Participation in the STAR Kids program does not change the way dual eligible clients receive Medicare services.

(f) Individuals younger than 21 years of age [~~birth through 20~~] who participate in the Medicaid Buy-In for Children Program or the Medicaid Buy-In Program must enroll in STAR Kids.

(g) FFCC members at least [~~ages~~] 18 years of age but younger than 21 years of age [~~through 20~~] may choose to transfer from STAR Health to STAR Kids if they meet the criteria in subsections (b), (c), (e), or (f) of this section.

[~~(h) Except as provided in subsection (d), children receiving medical assistance through the Texas Department of Family and Protective Services Adoption Assistance Program, as described under Title 40 of the Texas Administrative Code, Chapter 700, Subchapter H (relating to Adoption Assistance Program); or Permanency Care Assistance Program, as described under Title 40 of the Texas Administrative Code, Chapter 700, Subchapter J, Division 2 (relating to Permanency Care Assistance Program) must enroll in STAR Kids if they meet one or more of the criteria in subsections (a), (b), (c), or (e) of this section.~~]

(h) [~~(i)~~] A STAR Kids member has [~~Medicaid clients have~~] a choice among at least two MCOs.

(i) Except as provided in subsection (d) of this section, a child or young adult, from birth through the month of his or her 21st birthday, who is enrolled in the Adoption Assistance Program or the Permanency Care Assistance Program and who meets one or more of the following criteria is eligible to participate in the STAR Kids program:

(1) receives Social Security Income (SSI);

(2) received SSI before becoming eligible for the Adoption Assistance Program or the Permanency Care Assistance Program;

(3) is enrolled in a Medicaid 1915(c) waiver; or

(4) is enrolled in Medicare.

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

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TITLE 19. EDUCATION

PART 2. TEXAS EDUCATION AGENCY

CHAPTER 102. EDUCATIONAL PROGRAMS
SUBCHAPTER EE. COMMISSIONER'S RULES CONCERNING PILOT PROGRAMS

19 TAC §102.1054

The Texas Education Agency (TEA) proposes the repeal of §102.1054, concerning the intensive summer pilot program. The proposed repeal would remove the rule because its authorizing statute no longer exists.

BACKGROUND INFORMATION AND JUSTIFICATION: The 80th Texas Legislature, 2007, added Texas Education Code (TEC), §29.098, to establish a pilot program for students identified as being at risk of dropping out of school. The statute required the commissioner of education to adopt rules for awarding grants to participating campuses to provide intensive academic instruction during the summer.

Section 102.1054, adopted effective July 31, 2008, implemented the statute by establishing eligibility criteria, application requirements, and provisions for funding and operation of the intensive summer pilot program.

House Bill 3, 86th Texas Legislature, 2019, removed TEC, §29.098. The proposed repeal of §102.1054 is necessary since the authorizing statute no longer exists.

FISCAL IMPACT: Megan Aghazadian, deputy commissioner for operations, has determined that for the first five-year period the proposal is in effect there are no additional costs to state or local government, including school districts and open-enrollment charter schools, required to comply with the proposal.

LOCAL EMPLOYMENT IMPACT: The proposal has no effect on local economy; therefore, no local employment impact statement is required under Texas Government Code, §2001.022.

SMALL BUSINESS, MICROBUSINESS, AND RURAL COMMUNITY IMPACT: The proposal has no direct adverse economic impact for small businesses, microbusinesses, or rural communities; therefore, no regulatory flexibility analysis, specified in Texas Government Code, §2006.002, is required.

COST INCREASE TO REGULATED PERSONS: The proposal does not impose a cost on regulated persons, another state agency, a special district, or a local government and, therefore, is not subject to Texas Government Code, §2001.0045.

TAKINGS IMPACT ASSESSMENT: The proposal does not impose a burden on private real property and, therefore, does not constitute a taking under Texas Government Code, §2007.043.

GOVERNMENT GROWTH IMPACT: TEA staff prepared a Government Growth Impact Statement assessment for this proposed rulemaking. During the first five years the proposed rulemaking

would be in effect, it would repeal an existing regulation by removing a rule for which statutory authority no longer exists.

The proposed rulemaking would not create or eliminate a government program; would not require the creation of new employee positions or elimination of existing employee positions; would not require an increase or decrease in future legislative appropriations to the agency; would not require an increase or decrease in fees paid to the agency; would not create a new regulation; would not expand or limit an existing regulation; would not increase or decrease the number of individuals subject to its applicability; and would not positively or adversely affect the state's economy.

PUBLIC BENEFIT AND COST TO PERSONS: Ms. Aghazadian has determined that for each year of the first five years the proposal is in effect, the public benefit anticipated as a result of enforcing the proposal would be removing a rule for which statutory authority no longer exists. There is no anticipated economic cost to persons who are required to comply with the proposal.

DATA AND REPORTING IMPACT: The proposal would have no data or reporting impact.

PRINCIPAL AND CLASSROOM TEACHER PAPERWORK REQUIREMENTS: TEA has determined that the proposal would not require a written report or other paperwork to be completed by a principal or classroom teacher.

PUBLIC COMMENTS: The public comment period on the proposal begins April 2, 2021, and ends May 3, 2021. A request for a public hearing on the proposal submitted under the Administrative Procedure Act must be received by the commissioner of education not more than 14 calendar days after notice of the proposal has been published in the *Texas Register* on April 2, 2021. A form for submitting public comments is available on the TEA website at https://tea.texas.gov/About_TEA/Laws_and_Rules/Commissioner_Rules_(TAC)/Proposed_Commissioner_of_Education_Rules/.

STATUTORY AUTHORITY. The repeal is proposed under House Bill 3, §4.001, which repealed Texas Education Code, §29.098, which required the commissioner to establish by rule procedures for awarding grants for intensive summer programs.

CROSS REFERENCE TO STATUTE. The repeal implements House Bill 3, §4.001, 86th Texas Legislature, 2019.

§102.1054. Intensive Summer Pilot Program.

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

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Cristina De La Fuente-Valadez
Director, Rulemakikng
Texas Education Agency
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SUBCHAPTER FF. COMMISSIONER'S RULES CONCERNING EDUCATOR AWARD PROGRAMS

19 TAC §102.1071

The Texas Education Agency (TEA) proposes the repeal of §102.1071, concerning the Governor's Educator Excellence Award Program--Texas Educator Excellence Grant. The proposed repeal would remove the rule because its authorizing statute no longer exists.

BACKGROUND INFORMATION AND JUSTIFICATION: The 79th Texas Legislature, 2005, added Texas Education Code (TEC), Chapter 21, Subchapter N, to establish a program whereby classroom teachers and other campus personnel could receive an incentive award from an eligible campus through a student achievement program. The statute required that the commissioner establish a grant award program and adopt rules for developing a campus incentive plan and the awarding of funds.

Section 102.1071, adopted effective January 9, 2007, implemented TEC, Chapter 21, Subchapter N, by establishing the Governor's Educator Excellence Award Program--Texas Educator Excellence Grant.

House Bill 3646, 81st Texas Legislature, 2009, removed TEC, Chapter 21, Subchapter N. The proposed repeal of §102.1071 is necessary since the authorizing statute no longer exists.

FISCAL IMPACT: Megan Aghazadian, deputy commissioner for operations, has determined that for the first five-year period the proposal is in effect there are no additional costs to state or local government, including school districts and open-enrollment charter schools, required to comply with the proposal.

LOCAL EMPLOYMENT IMPACT: The proposal has no effect on local economy; therefore, no local employment impact statement is required under Texas Government Code, §2001.022.

SMALL BUSINESS, MICROBUSINESS, AND RURAL COMMUNITY IMPACT: The proposal has no direct adverse economic impact for small businesses, microbusinesses, or rural communities; therefore, no regulatory flexibility analysis, specified in Texas Government Code, §2006.002, is required.

COST INCREASE TO REGULATED PERSONS: The proposal does not impose a cost on regulated persons, another state agency, a special district, or a local government and, therefore, is not subject to Texas Government Code, §2001.0045.

TAKINGS IMPACT ASSESSMENT: The proposal does not impose a burden on private real property and, therefore, does not constitute a taking under Texas Government Code, §2007.043.

GOVERNMENT GROWTH IMPACT: TEA staff prepared a Government Growth Impact Statement assessment for this proposed rulemaking. During the first five years the proposed rulemaking would be in effect, it would repeal an existing regulation by removing a rule for which statutory authority no longer exists.

The proposed rulemaking would not create or eliminate a government program; would not require the creation of new employee positions or elimination of existing employee positions; would not require an increase or decrease in future legislative appropriations to the agency; would not require an increase or decrease in fees paid to the agency; would not create a new regulation; would not expand or limit an existing regulation; would not increase or decrease the number of individuals subject to its applicability; and would not positively or adversely affect the state's economy.

PUBLIC BENEFIT AND COST TO PERSONS: Ms. Aghazadian has determined that for each year of the first five years the proposal is in effect, the public benefit anticipated as a result of enforcing the proposal would be removing a rule for which statutory authority no longer exists. There is no anticipated economic cost to persons who are required to comply with the proposal.

DATA AND REPORTING IMPACT: The proposal would have no data or reporting impact.

PRINCIPAL AND CLASSROOM TEACHER PAPERWORK REQUIREMENTS: TEA has determined that the proposal would not require a written report or other paperwork to be completed by a principal or classroom teacher.

PUBLIC COMMENTS: The public comment period on the proposal begins April 2, 2021, and ends May 3, 2021. A request for a public hearing on the proposal submitted under the Administrative Procedure Act must be received by the commissioner of education not more than 14 calendar days after notice of the proposal has been published in the *Texas Register* on April 2, 2021. A form for submitting public comments is available on the TEA website at https://tea.texas.gov/About_TEA/Laws_and_Rules/Commissioner_Rules_(TAC)/Proposed_Commissioner_of_Education_Rules/.

STATUTORY AUTHORITY. The repeal is proposed under House Bill (HB) 3646, §105, 81st Texas Legislature, 2009, which repealed Texas Education Code (TEC), §21.652, which required the commissioner by rule to establish a student achievement award program under which an eligible campus may receive a grant from the agency in the manner provided by TEC, Chapter 21, Subchapter N, and adopt program guidelines for a campus to follow in developing a campus incentive plan. HB 3646 also repealed TEC, §21.658, which required the commissioner to adopt rules necessary to administer TEC, Chapter 21, Subchapter N.

CROSS REFERENCE TO STATUTE. The repeal implements House Bill 3646, §105, 81st Texas Legislature, 2009.

§102.1071. Governor's Educator Excellence Award Program--Texas Educator Excellence Grant.

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

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CHAPTER 109. BUDGETING, ACCOUNTING, AND AUDITING
SUBCHAPTER CC. COMMISSIONER'S RULES CONCERNING FEDERAL FISCAL COMPLIANCE AND REPORTING

19 TAC §109.3001, §109.3003

The Texas Education Agency (TEA) proposes amendments to §109.3001 and §109.3003, concerning federal fiscal compliance and reporting. The proposed amendments would modify the existing rules to reflect changes to federal statutes, regulations, non-regulatory guidance, and delegation agreements.

BACKGROUND INFORMATION AND JUSTIFICATION: Section 109.3001, Local Maintenance of Effort, outlines TEA's responsibility to monitor compliance by local educational agencies (LEAs) with Individuals with Disabilities Education Act, Part B (IDEA-B) LEA maintenance of effort (MOE) and Every Student Succeeds Act (ESSA) LEA MOE. The proposed amendment to §109.3001 would update the statutory and regulatory citations and remove the handbooks adopted as Figure: 19 TAC §109.3001(c)(1) and Figure: 19 TAC §109.3001(c)(2). TEA has determined that the handbooks do not need to be included in rule since they do not create new regulations or rules and instead provide guidance on how TEA applies existing federal statutes and regulations to determine LEA compliance.

Section 109.3003, Indirect Cost Rates, outlines TEA's responsibility to calculate and issue indirect cost rates to LEAs and education service centers. The proposed amendment would update both the rule and Figure: 19 TAC §109.3003(d) to reflect revised statutory citations and a new delegation agreement from the United States Department of Education. In addition, Figure: 19 TAC §109.3003(d) would only include information on how organizations would request and apply for an indirect cost rate. Information on how subrecipients use their indirect cost rates would be removed since that information is already outlined in existing federal regulations and nonregulatory guidance.

FISCAL IMPACT: Mike Meyer, deputy commissioner for finance, has determined that for the first five-year period the proposal is in effect there are no additional costs to state or local government, including school districts and open-enrollment charter schools, required to comply with the proposal.

LOCAL EMPLOYMENT IMPACT: The proposal has no effect on local economy; therefore, no local employment impact statement is required under Texas Government Code, §2001.022.

SMALL BUSINESS, MICROBUSINESS, AND RURAL COMMUNITY IMPACT: The proposal has no direct adverse economic impact for small businesses, microbusinesses, or rural communities; therefore, no regulatory flexibility analysis, specified in Texas Government Code, §2006.002, is required.

COST INCREASE TO REGULATED PERSONS: The proposal does not impose a cost on regulated persons, another state agency, a special district, or a local government and, therefore, is not subject to Texas Government Code, §2001.0045.

TAKINGS IMPACT ASSESSMENT: The proposal does not impose a burden on private real property and, therefore, does not constitute a taking under Texas Government Code, §2007.043.

GOVERNMENT GROWTH IMPACT: TEA staff prepared a Government Growth Impact Statement assessment for this proposed rulemaking. During the first five years the proposed rulemaking would be in effect, it would limit an existing regulation by removing requirements and information addressed by federal law and nonregulatory guidance.

The proposed rulemaking would not create or eliminate a government program; would not require the creation of new employee positions or elimination of existing employee positions; would not require an increase or decrease in future legislative appropriations to the agency; would not require an increase or

decrease in fees paid to the agency; would not create a new regulation; would not expand or repeal an existing regulation; would not increase or decrease the number of individuals subject to its applicability; and would not positively or adversely affect the state's economy.

PUBLIC BENEFIT AND COST TO PERSONS: Mr. Meyer has determined that for each year of the first five years the proposal is in effect, the public benefit anticipated as a result of enforcing the proposal would be ensuring that rule language is based on current law. There is no anticipated economic cost to persons who are required to comply with the proposal.

DATA AND REPORTING IMPACT: The proposal would have no data or reporting impact.

PRINCIPAL AND CLASSROOM TEACHER PAPERWORK REQUIREMENTS: TEA has determined that the proposal would not require a written report or other paperwork to be completed by a principal or classroom teacher.

PUBLIC COMMENTS: The public comment period on the proposal begins April 2, 2021, and ends May 3, 2021. A request for a public hearing on the proposal submitted under the Administrative Procedure Act must be received by the commissioner of education not more than 14 calendar days after notice of the proposal has been published in the *Texas Register* on April 2, 2021. A form for submitting public comments is available on the TEA website at https://tea.texas.gov/About_TEA/Laws_and_Rules/Commissioner_Rules_(TAC)/Proposed_Commissioner_of_Education_Rules/.

STATUTORY AUTHORITY. The amendments are proposed under Texas Education Code (TEC), §7.021(b)(1), which requires the Texas Education Agency (TEA) to administer and monitor compliance with education programs required by federal or state law, including federal funding; and TEC, §7.031(a), which establishes that TEA may seek, accept, and distribute grants awarded by the federal government, subject to the limitations or conditions imposed by the terms of the grants or by other law.

CROSS REFERENCE TO STATUTE. The amendments implement Texas Education Code, §7.021(b)(1) and §7.031(a).

§109.3001. Local Maintenance of Effort.

(a) In accordance with the Texas Education Code, §7.021, the Texas Education Agency [~~(TEA)~~] shall administer and monitor compliance with education programs required by federal or state law, including federal funding and state funding for those programs.

(b) The following terms have the following meanings when used in this subchapter.

(1) Maintenance of Effort (MOE) for a grant under the Individuals with Disabilities Education Act, Part B (IDEA-B)--This term has the meaning assigned by 34 Code of Federal Regulations (CFR), §300.203(a).

(2) MOE for a grant under the Every Student Succeeds Act (ESSA) [~~No Child Left Behind Act (NCLB)~~] --This term is generally defined by Public Law 114-95, Title VIII, Part F, Subpart 2, §8521 [~~107-110, Title IX, Part E, Subpart 2, §9521~~].

(c) Each local educational [~~education~~] agency (LEA) that expends federal IDEA-B or ESSA [~~NCLB~~] funds must comply with established MOE requirements developed in conjunction with federal statutes, regulations, and guidance from the United States Department of Education [~~(USDE)~~]. The methods of determining compliance, the consequences of noncompliance, and allowable exceptions to the MOE requirements are outlined in the statutes specified in subsection (b)(1) and (2) of this section [~~described in the figures provided in paragraphs (1) and (2) of this subsection~~].

[~~(1) The specific MOE requirements for a grant under the IDEA-B are described in the *IDEA-B LEA MOE Guidance Handbook* provided in this paragraph.~~]
[~~Figure: 19 TAC §109.3001(c)(1)~~]

[~~(2) The specific MOE requirements for a grant under the NCLB are described in the *NCLB LEA MOE Guidance Handbook* provided in this paragraph.~~]
[~~Figure: 19 TAC §109.3001(c)(2)~~]

(d) If an LEA provides a Medicaid-eligible student with a Medicaid service that is specified in the student's individualized education program, the LEA may request reimbursement for that service through Medicaid's School Health and Related Services (SHARS) program. The LEA is reimbursed the federal portion of the amount it expended on the service based on the Federal Medicaid Assistance Percentage rate Medicaid has defined. In accordance with 34 CFR, §300.154(g)(2), if the reimbursement is expended on special education services, that expenditure must be excluded from the calculation of state/local expenditures for purposes of calculating IDEA-B LEA MOE compliance (34 CFR, §300.154(g)(2)).

[~~(d) Guidance provided in the handbooks described in subsection (c)(1) and (2) of this section will be updated annually as necessary by the commissioner of education to align with subsequent updates, modifications, and amendments to the statutory authority and USDE guidance.~~]

[~~(e) For determining compliance with MOE requirements, the TEA will use the handbooks provided in subsection (c)(1) and (2) of this section instead of:~~]

[~~(1) the software in PEIMS EDIT+ containing a formula to allocate costs recorded in Program Intent Code 99, Undistributed, according to instructional FTEs (as reported in PEIMS) assigned to Basic and Enhanced Program Intent Codes; or~~]

[~~(2) the software in EDIT+ containing a formula to allocate costs recorded in Organization Code 999, Undistributed.~~]

[~~(f) If the LEA receives School Health and Related Services (SHARS) reimbursements, funds received represent reimbursements to the LEA for school-based health services, which are provided to special education students enrolled in the Medicaid Program. Additional guidance concerning the treatment of SHARS direct and indirect cost reimbursements is documented in the *IDEA-B LEA MOE Guidance Handbook* provided in subsection (c)(1) of this section.~~]

(e) [~~(g)~~] To the extent that this section conflicts with any other commissioner or State Board of Education rule, including the Financial Accountability System Resource Guide, the provisions of this section control.

§109.3003. Indirect Cost Rates.

(a) Pursuant to authorization in 34 Code of Federal Regulations (CFR), §75.561(b) and §76.561(b), the Texas Education Agency (TEA) has been delegated the authority by the United States Department of Education (USDE) to issue indirect cost rates to local educational agencies (LEAs) and education service centers (ESCs) [~~review indirect cost applications and to approve indirect cost rates~~].

(b) Pursuant to 34 CFR, §75.561(b) and §76.561(b), to [~~To~~] recover any indirect costs for the administration of federal grants, an entity must have an approved indirect cost rate. Indirect cost rates will be issued for a one-year period from July 1 to June 30. A new indirect cost rate must be requested each [~~obtained for every fiscal~~] year.

(c) For the one-year period [~~fiscal year~~] an entity has been issued an indirect cost rate, it can claim indirect cost revenue on applicable grants during that period [~~in that fiscal year~~]. As indirect cost revenues are earned in the Special Revenue Fund on federally funded grants, these revenues can be transferred from the Special Revenue Fund to the General Fund. After the indirect cost revenue has been recorded in the General Fund, the revenues can be used for any legal purpose.

(d) Guidance concerning the process for requesting an indirect cost rate for entities where TEA is the cognizant agency, including LEAs and ESCs, [~~rates~~] has been developed by [~~the~~] TEA in conjunction with federal statutes and guidance from [~~the~~] USDE [~~to be used for various entities for which the TEA is the cognizant agency~~]. The definitions, standards, and procedures to request an [~~used to govern~~] indirect cost rate are outlined [~~rates are described~~] in the *Indirect Cost Rate Guidance Handbook* provided in this subsection.
Figure: 19 TAC §109.3003(d)
[~~Figure: 19 TAC §109.3003(d)~~]

(e) Guidance provided in the handbook described in subsection (d) of this section will be updated [~~annually~~] as necessary by the commissioner of education to align with subsequent updates, modifications, and amendments to the statutory authority and USDE guidance.

(f) To the extent that this section conflicts with any other commissioner or State Board of Education rule, including the Financial Accountability System Resource Guide, the provisions of this section control.

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

Filed with the Office of the Secretary of State on March 22, 2021.

TRD-202101197
Cristina De La Fuente-Valadez
Director, Rulemaking
Texas Education Agency
Earliest possible date of adoption: May 2, 2021
For further information, please call: (512) 475-1497

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TITLE 22. EXAMINING BOARDS

PART 15. TEXAS STATE BOARD OF PHARMACY

CHAPTER 291. PHARMACIES

SUBCHAPTER A. ALL CLASSES OF PHARMACIES

22 TAC §291.11

The Texas State Board of Pharmacy proposes amendments to §291.11, concerning Operation of a Pharmacy. The amendments, if adopted, correct citation references and a short title reference.

Allison Vordenbaumen Benz, R.Ph., M.S., Executive Director/Secretary, has determined that, for the first five-year period the rules are in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule. Ms. Benz has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the amendments will be correct and clear regulatory language. There is no anticipated adverse economic impact on large, small or micro-businesses (pharmacies), rural communities, or local or state employment. Therefore, an economic impact statement and regulatory flexibility analysis are not required.

For each year of the first five years the proposed amendments will be in effect, Ms. Benz has determined the following:

(1) The proposed amendments do not create or eliminate a government program;

(2) Implementation of the proposed amendments does not require the creation of new employee positions or the elimination of existing employee positions;

(3) Implementation of the proposed amendments does not require an increase or decrease in the future legislative appropriations to the agency;

(4) The proposed amendments do not require an increase or decrease in fees paid to the agency;

(5) The proposed amendments do not create a new regulation;

(6) The proposed amendments do not limit or expand an existing regulation;

(7) The proposed amendments do not increase or decrease the number of individuals subject to the rule's applicability; and

(8) The proposed amendments do not positively or adversely affect this state's economy.

Written comments on the amendments may be submitted to Megan G. Holloway, Deputy General Counsel, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-500, Austin, Texas 78701, FAX (512) 305-8061. Comments must be received by 5:00 p.m., May 4, 2021.

The amendments are proposed 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 these amendments: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

§291.11. Operation of a Pharmacy.

(a) For the purposes of §565.002(a)(7) [~~§565.002(7)~~] of the Texas Pharmacy Act, the following words and terms shall be defined as follows.

(1) "Failure to engage in the business described in the application for a license" means the holder of a pharmacy license has not commenced operating the pharmacy within six months of the date of issuance of the license.

(2) "Ceased to engage in the business described in the application for a license" means the holder of a pharmacy license, once it has been in operation, discontinues operating the pharmacy for a period of 30 days or longer unless the pharmacy experiences a fire or disaster, in which case the pharmacy must comply with §291.3(g) [~~§291.3(f)~~] of this title (relating to Required Notifications).

(b) For the purposes of this section, the term "operating the pharmacy" means the pharmacy shall demonstrate observable pharmacy business activity on a regular, routine basis, including a suffi-

cient number of transactions of receiving, processing, or dispensing prescription drug orders or medication drug orders.

(c) No person may operate a pharmacy in a personal residence.

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

Filed with the Office of the Secretary of State on March 15, 2021.

TRD-202101088
Allison Vordenbaumen Benz, R.Ph., M.S.
Executive Director
Texas State Board of Pharmacy
Earliest possible date of adoption: May 2, 2021
For further information, please call: (512) 305-8010

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SUBCHAPTER B. COMMUNITY PHARMACY (CLASS A)

22 TAC §291.34

The Texas State Board of Pharmacy proposes amendments to §291.34 concerning Records. The amendments, if adopted, clarify that a pharmacist may electronically sign the data entry attestation statement and update references to DEA 222 form requirements to be consistent with federal regulations.

Allison Vordenbaumen Benz, R.Ph., M.S., Executive Director/Secretary, has determined that, for the first five-year period the rules are in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule. Ms. Benz has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the amendments will be to provide clearer regulatory language and to ensure consistency between Board rules and federal regulations. There is no anticipated adverse economic impact on large, small or micro-businesses (pharmacies), rural communities, or local or state employment. Therefore, an economic impact statement and regulatory flexibility analysis are not required.

For each year of the first five years the proposed amendments will be in effect, Ms. Benz has determined the following:

(1) The proposed amendments do not create or eliminate a government program;

(2) Implementation of the proposed amendments does not require the creation of new employee positions or the elimination of existing employee positions;

(3) Implementation of the proposed amendments does not require an increase or decrease in the future legislative appropriations to the agency;

(4) The proposed amendments do not require an increase or decrease in fees paid to the agency;

(5) The proposed amendments do not create a new regulation;

(6) The proposed amendments do limit an existing regulation;

(7) The proposed amendments do not increase or decrease the number of individuals subject to the rule's applicability; and

(8) The proposed amendments do not positively or adversely affect this state's economy.

Written comments on the amendments may be submitted to Megan G. Holloway, Deputy General Counsel, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-500, Austin, Texas 78701, FAX (512) 305-8061. Comments must be received by 5:00 p.m., May 4, 2021.

The amendments are proposed 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 these amendments: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

§291.34. Records.

(a) Maintenance of records.

(1) Every inventory or other record required to be kept under the provisions of Subchapter B of this chapter (relating to Community Pharmacy (Class A)) shall be:

(A) kept by the pharmacy at the pharmacy's licensed location 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 to other authorized local, state, or federal law enforcement agencies; and

(B) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy. 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 section, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.

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

(3) Records of controlled substances, other than prescription drug orders, listed in Schedules III-V shall be maintained separately or readily retrievable from all other records of the pharmacy. For purposes of this subsection, readily retrievable means that the controlled substances shall be asterisked, red-lined, or in some other manner readily identifiable apart from all other items appearing on the record.

(4) 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 system or direct imaging system provided:

(A) the records maintained in the alternative system contain all of the information required on the manual record; and

(B) the data processing 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.

(b) Prescriptions.

(1) Professional responsibility.

(A) Pharmacists shall exercise sound professional judgment with respect to the accuracy and authenticity of any prescription drug order they dispense. If the pharmacist questions the accuracy or

authenticity of a prescription drug order, he/she shall verify the order with the practitioner prior to dispensing.

(B) Prior to dispensing a prescription, pharmacists shall determine, in the exercise of sound professional judgment, that the prescription is a valid prescription. A pharmacist may not dispense a prescription drug unless the pharmacist complies with the requirements of §562.056 and §562.112 of the Act, and §291.29 of this title (relating to Professional Responsibility of Pharmacists)..

(C) Subparagraph (B) of this paragraph does not prohibit a pharmacist from dispensing a prescription when a valid patient-practitioner relationship is not present in an emergency situation (e.g., a practitioner taking calls for the patient's regular practitioner).

(D) The owner of a Class A pharmacy shall have responsibility for ensuring its agents and employees engage in appropriate decisions regarding dispensing of valid prescriptions as set forth in §562.112 of the Act.

(2) Written prescription drug orders.

(A) Practitioner's signature.

(i) Dangerous drug prescription orders. Written prescription drug orders shall be:

(I) manually signed by the practitioner; or

(II) electronically signed by the practitioner using a system that electronically replicates the practitioner's manual signature on the written prescription, provided:

(-a-) that security features of the system require the practitioner to authorize each use; and

(-b-) the prescription is printed on paper that is designed to prevent unauthorized copying of a completed prescription and to prevent the erasure or modification of information written on the prescription by the prescribing practitioner. (For example, the paper contains security provisions against copying that results in some indication on the copy that it is a copy and therefore render the prescription null and void.)

(ii) Controlled substance prescription orders. Prescription drug orders for Schedules II, III, IV, or V controlled substances shall be manually signed by the practitioner. Prescription drug orders for Schedule II controlled substances shall be issued on an official prescription form as required by the Texas Controlled Substances Act, §481.075.

(iii) Other provisions for a practitioner's signature.

(I) A practitioner may sign a prescription drug order in the same manner as he would sign a check or legal document, e.g., J.H. Smith or John H. Smith.

(II) Rubber stamped signatures may not be used.

(III) The prescription drug order may not be signed by a practitioner's agent but may be prepared by an agent for the signature of a practitioner. However, the prescribing practitioner is responsible in case the prescription drug order does not conform in all essential respects to the law and regulations.

(B) Prescription drug orders written by practitioners in another state.

(i) Dangerous drug prescription orders. A pharmacist may dispense prescription drug orders for dangerous drugs issued by practitioners in a state other than Texas in the same manner as prescription drug orders for dangerous drugs issued by practitioners in Texas are dispensed.

(ii) Controlled substance prescription drug orders.

(I) A pharmacist may dispense prescription drug orders for Schedule II controlled substances issued by a practitioner in another state provided:

(-a-) the prescription is dispensed as specified in §315.9 of this title (relating to Pharmacy Responsibility - Out-of-State Practitioner - Effective September 1, 2016);

(-b-) the prescription drug order is an original written prescription issued by a person practicing in another state and licensed by another state as a physician, dentist, veterinarian, or podiatrist, who has a current federal Drug Enforcement Administration (DEA) registration number, and who may legally prescribe Schedule II controlled substances in such other state; and

(-c-) the prescription drug order is not dispensed after the end of the twenty-first day after the date on which the prescription is issued.

(II) A pharmacist may dispense prescription drug orders for controlled substances in Schedules III, IV, or V issued by a physician, dentist, veterinarian, or podiatrist in another state provided:

(-a-) the prescription drug order is issued by a person practicing in another state and licensed by another state as a physician, dentist, veterinarian, or podiatrist, who has a current federal DEA registration number, and who may legally prescribe Schedules III, IV, or V controlled substances in such other state;

(-b-) the prescription drug order is not dispensed or refilled more than six months from the initial date of issuance and may not be refilled more than five times; and

(-c-) if there are no refill instructions on the original prescription drug order (which shall be interpreted as no refills authorized) or if all refills authorized on the original prescription drug order have been dispensed, a new prescription drug order is obtained from the prescribing practitioner prior to dispensing any additional quantities of controlled substances.

(C) Prescription drug orders written by practitioners in the United Mexican States or the Dominion of Canada.

(i) Controlled substance prescription drug orders. A pharmacist may not dispense a prescription drug order for a Schedule II, III, IV, or V controlled substance issued by a practitioner in the Dominion of Canada or the United Mexican States.

(ii) Dangerous drug prescription drug orders. A pharmacist may dispense a dangerous drug prescription issued by a person licensed in the Dominion of Canada or the United Mexican States as a physician, dentist, veterinarian, or podiatrist provided:

(I) the prescription drug order is an original written prescription; and

(II) if there are no refill instructions on the original written prescription drug order (which shall be interpreted as no refills authorized) or if all refills authorized on the original written prescription drug order have been dispensed, a new written prescription drug order shall be obtained from the prescribing practitioner prior to dispensing any additional quantities of dangerous drugs.

(D) Prescription drug orders issued by an advanced practice registered nurse, physician assistant, or pharmacist.

(i) A pharmacist may dispense a prescription drug order that is:

(I) issued by an advanced practice registered nurse or physician assistant provided the advanced practice registered

nurse or physician assistant is practicing in accordance with Subtitle B, Chapter 157, Occupations Code; and

(II) for a dangerous drug and signed by a pharmacist under delegated authority of a physician as specified in Subtitle B, Chapter 157, Occupations Code.

(ii) Each practitioner shall designate in writing the name of each advanced practice registered nurse or physician assistant authorized to issue a prescription drug order pursuant to Subtitle B, Chapter 157, Occupations Code. A list of the advanced practice registered nurses or physician assistants designated by the practitioner must be maintained in the practitioner's usual place of business. On request by a pharmacist, a practitioner shall furnish the pharmacist with a copy of the written authorization for a specific advanced practice registered nurse or physician assistant.

(E) Prescription drug orders for Schedule II controlled substances. No Schedule II controlled substance may be dispensed without a written prescription drug order of a practitioner on an official prescription form as required by the Texas Controlled Substances Act, §481.075.

(3) Oral prescription drug orders.

(A) An oral prescription drug order for a controlled substance from a practitioner or a practitioner's designated agent may only be received by a pharmacist or a pharmacist-intern under the direct supervision of a pharmacist.

(B) A practitioner shall designate in writing the name of each agent authorized by the practitioner to communicate prescriptions orally for the practitioner. The practitioner shall maintain at the practitioner's usual place of business a list of the designated agents. The practitioner shall provide a pharmacist with a copy of the practitioner's written authorization for a specific agent on the pharmacist's request.

(C) A pharmacist may not dispense an oral prescription drug order for a dangerous drug or a controlled substance issued by a practitioner licensed in the Dominion of Canada or the United Mexican States unless the practitioner is also licensed in Texas.

(4) Electronic prescription drug orders.

(A) Dangerous drug prescription orders.

(i) An electronic prescription drug order for a dangerous drug may be transmitted by a practitioner or a practitioner's designated agent:

(I) directly to a pharmacy; or

(II) through the use of a data communication device provided:

(-a-) the confidential prescription information is not altered during transmission; and

(-b-) confidential patient information is not accessed or maintained by the operator of the data communication device other than for legal purposes under federal and state law.

(ii) A practitioner shall designate in writing the name of each agent authorized by the practitioner to electronically transmit prescriptions for the practitioner. The practitioner shall maintain at the practitioner's usual place of business a list of the designated agents. The practitioner shall provide a pharmacist with a copy of the practitioner's written authorization for a specific agent on the pharmacist's request.

(B) Controlled substance prescription orders. A pharmacist may only dispense an electronic prescription drug order for a Schedule II, III, IV, or V controlled substance in compliance with federal and state laws and the rules of the Drug Enforcement Administration outlined in Part 1300 of the Code of Federal Regulations.

(C) Prescriptions issued by a practitioner licensed in the Dominion of Canada or the United Mexican States. A pharmacist may not dispense an electronic prescription drug order for a dangerous drug or controlled substance issued by a practitioner licensed in the Dominion of Canada or the United Mexican States unless the practitioner is also licensed in Texas.

(5) Facsimile (faxed) prescription drug orders.

(A) A pharmacist may dispense a prescription drug order for a dangerous drug transmitted to the pharmacy by facsimile.

(B) A pharmacist may dispense a prescription drug order for a Schedule III-V controlled substance transmitted to the pharmacy by facsimile provided the prescription is manually signed by the practitioner and not electronically signed using a system that electronically replicates the practitioner's manual signature on the prescription drug order.

(C) A pharmacist may not dispense a facsimile prescription drug order for a dangerous drug or controlled substance issued by a practitioner licensed in the Dominion of Canada or the United Mexican States unless the practitioner is also licensed in Texas.

(6) Original prescription drug order records.

(A) Original prescriptions may be dispensed only in accordance with the prescriber's authorization as indicated on the original prescription drug order, including clarifications to the order given [~~to the pharmacist~~] by the practitioner or the practitioner's agent and recorded on the prescription.

(B) Notwithstanding subparagraph (A) of this paragraph, a pharmacist may dispense a quantity less than indicated on the original prescription drug order at the request of the patient or patient's agent.

(C) Original prescriptions shall be maintained by the pharmacy in numerical order and remain legible for a period of two years from the date of filling or the date of the last refill dispensed.

(D) If an original prescription drug order is changed, such prescription order shall be invalid and of no further force and effect; if additional drugs are to be dispensed, a new prescription drug order with a new and separate number is required. However, an original prescription drug order for a dangerous drug may be changed in accordance with paragraph (10) of this subsection relating to accelerated refills.

(E) Original prescriptions shall be maintained in three separate files as follows:

(i) prescriptions for controlled substances listed in Schedule II;

(ii) prescriptions for controlled substances listed in Schedules III-V; and

(iii) prescriptions for dangerous drugs and nonprescription drugs.

(F) Original prescription records other than prescriptions for Schedule II controlled substances may be stored in a system that is capable of producing a direct image of the original prescription record, e.g., a digitalized imaging system. If original prescription records are stored in a direct imaging system, the following is applicable:

(i) the record of refills recorded on the original prescription must also be stored in this system;

(ii) the original prescription records must be maintained in numerical order and separated in three files as specified in subparagraph (D) of this paragraph; and

(iii) the pharmacy must provide immediate access to equipment necessary to render the records easily readable.

(7) Prescription drug order information.

(A) All original prescriptions shall bear:

(i) the name of the patient, or if such drug is for an animal, the species of such animal and the name of the owner;

(ii) the address of the patient; provided, however, that a prescription for a dangerous drug is not required to bear the address of the patient if such address is readily retrievable on another appropriate, uniformly maintained pharmacy record, such as medication records;

(iii) the name, address and telephone number of the practitioner at the practitioner's usual place of business, legibly printed or stamped, and if for a controlled substance, the DEA registration number of the practitioner;

(iv) the name and strength of the drug prescribed;

(v) the quantity prescribed numerically, and if for a controlled substance:

(I) numerically, followed by the number written as a word, if the prescription is written;

(II) numerically, if the prescription is electronic; or

(III) if the prescription is communicated orally or telephonically, as transcribed by the receiving pharmacist;

(vi) directions for use;

(vii) the intended use for the drug unless the practitioner determines the furnishing of this information is not in the best interest of the patient;

(viii) the date of issuance;

(ix) if a faxed prescription:

(I) a statement that indicates that the prescription has been faxed (e.g., Faxed to); and

(II) if transmitted by a designated agent, the name of the designated agent;

(x) if electronically transmitted:

(I) the date the prescription drug order was electronically transmitted to the pharmacy, if different from the date of issuance of the prescription; and

(II) if transmitted by a designated agent, the name of the designated agent; and

(xi) if issued by an advanced practice nurse or physician assistant in accordance with Subtitle B, Chapter 157, Occupations Code:

(I) the name, address, telephone number, and if the prescription is for a controlled substance, the DEA number of the supervising practitioner; and

(II) the address and telephone number of the clinic where the prescription drug order was carried out or signed; and

(xii) if communicated orally or telephonically:

(I) the initials or identification code of the transcribing pharmacist; and

(II) the name of the prescriber or prescriber's agent communicating the prescription information.

(B) At the time of dispensing, a pharmacist is responsible for documenting the following information on either the original hardcopy prescription or in the pharmacy's data processing system:

(i) the unique identification number of the prescription drug order;

(ii) the initials or identification code of the dispensing pharmacist;

(iii) the initials or identification code of the pharmacy technician or pharmacy technician trainee performing data entry of the prescription, if applicable;

(iv) the quantity dispensed, if different from the quantity prescribed;

(v) the date of dispensing, if different from the date of issuance; and

(vi) the brand name or manufacturer of the drug or biological product actually dispensed, if the drug was prescribed by generic name or interchangeable biological name or if a drug or interchangeable biological product other than the one prescribed was dispensed pursuant to the provisions of the Act, Chapters 562 and 563.

(C) Prescription drug orders may be utilized as authorized in Title 40, Part 1, Chapter 19 of the Texas Administrative Code.

(i) A prescription drug order is not required to bear the information specified in subparagraph (A) of this paragraph if the drug is prescribed for administration to an ultimate user who is institutionalized in a licensed health care institution (e.g., nursing home, hospice, hospital). Such prescription drug orders must contain the following information:

(I) the full name of the patient;

(II) the date of issuance;

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

(IV) directions for use; and

(V) the signature(s) required by 40 TAC §19.1506.

(ii) Prescription drug orders for dangerous drugs shall not be dispensed following one year after the date of issuance unless the authorized prescriber renews the prescription drug order.

(iii) Controlled substances shall not be dispensed pursuant to a prescription drug order under this subparagraph.

(8) Refills.

(A) General information.

(i) Refills may be dispensed only in accordance with the prescriber's authorization as indicated on the original prescription drug order except as authorized in paragraph (10) of this subsection relating to accelerated refills.

(ii) If there are no refill instructions on the original prescription drug order (which shall be interpreted as no refills authorized) or if all refills authorized on the original prescription drug order have been dispensed, authorization from the prescribing practitioner shall be obtained prior to dispensing any refills and documented as specified in subsection (l) of this section.

(B) Refills of prescription drug orders for dangerous drugs or nonprescription drugs.

(i) Prescription drug orders for dangerous drugs or nonprescription drugs may not be refilled after one year from the date of issuance of the original prescription drug order.

(ii) If one year has expired from the date of issuance of an original prescription drug order for a dangerous drug or nonprescription drug, authorization shall be obtained from the prescribing practitioner prior to dispensing any additional quantities of the drug.

(C) Refills of prescription drug orders for Schedules III-V controlled substances.

(i) Prescription drug orders for Schedules III-V controlled substances may not be refilled more than five times or after six months from the date of issuance of the original prescription drug order, whichever occurs first.

(ii) If a prescription drug order for a Schedule III, IV, or V controlled substance has been refilled a total of five times or if six months have expired from the date of issuance of the original prescription drug order, whichever occurs first, a new and separate prescription drug order shall be obtained from the prescribing practitioner prior to dispensing any additional quantities of controlled substances.

(D) Pharmacist unable to contact prescribing practitioner. If a pharmacist is unable to contact the prescribing practitioner after a reasonable effort, a pharmacist may exercise his or her professional judgment in refilling a prescription drug order for a drug, other than a Schedule II controlled substance, without the authorization of the prescribing practitioner, provided:

(i) failure to refill the prescription might result in an interruption of a therapeutic regimen or create patient suffering;

(ii) the quantity of prescription drug dispensed does not exceed a 72-hour supply;

(iii) the pharmacist informs the patient or the patient's agent at the time of dispensing that the refill is being provided without such authorization and that authorization of the practitioner is required for future refills;

(iv) the pharmacist informs the practitioner of the emergency refill at the earliest reasonable time;

(v) the pharmacist maintains a record of the emergency refill containing the information required to be maintained on a prescription as specified in this subsection;

(vi) the pharmacist affixes a label to the dispensing container as specified in §291.33(c)(7) of this title (relating to Operational Standards) [~~of this title~~]; and

(vii) if the prescription was initially filled at another pharmacy, the pharmacist may exercise his or her professional judgment in refilling the prescription provided:

(I) the patient has the prescription container, label, receipt or other documentation from the other pharmacy that contains the essential information;

(II) after a reasonable effort, the pharmacist is unable to contact the other pharmacy to transfer the remaining prescription refills or there are no refills remaining on the prescription;

(III) the pharmacist, in his or her professional judgment, determines that such a request for an emergency refill is appropriate and meets the requirements of clause (i) of this subparagraph; and

(IV) the pharmacist complies with the requirements of clauses (ii) - (vi) of this subparagraph.

(E) Natural or man-made [~~manmade~~] disasters. If a natural or man-made [~~manmade~~] disaster has occurred that prohibits the pharmacist from being able to contact the practitioner, a pharmacist may exercise his or her professional judgment in refilling a prescription drug order for a drug, other than a Schedule II controlled substance, without the authorization of the prescribing practitioner, provided:

(i) failure to refill the prescription might result in an interruption of a therapeutic regimen or create patient suffering;

(ii) the quantity of prescription drug dispensed does not exceed a 30-day supply;

(iii) the governor of Texas has declared a state of disaster;

(iv) the board, through the executive director, has notified pharmacies that pharmacists may dispense up to a 30-day supply of prescription drugs;

(v) the pharmacist informs the patient or the patient's agent at the time of dispensing that the refill is being provided without such authorization and that authorization of the practitioner is required for future refills;

(vi) the pharmacist informs the practitioner of the emergency refill at the earliest reasonable time;

(vii) the pharmacist maintains a record of the emergency refill containing the information required to be maintained on a prescription as specified in this subsection;

(viii) the pharmacist affixes a label to the dispensing container as specified in §291.33(c)(7) of this title; and

(ix) if the prescription was initially filled at another pharmacy, the pharmacist may exercise his or her professional judgment in refilling the prescription provided:

(I) the patient has the prescription container, label, receipt or other documentation from the other pharmacy that contains the essential information;

(II) after a reasonable effort, the pharmacist is unable to contact the other pharmacy to transfer the remaining prescription refills or there are no refills remaining on the prescription;

(III) the pharmacist, in his or her professional judgment, determines that such a request for an emergency refill is appropriate and meets the requirements of clause (i) of this subparagraph; and

(IV) the pharmacist complies with the requirements of clauses (ii) - (viii) of this subparagraph.

(F) Auto-Refill Programs. A pharmacy may use a program that automatically refills prescriptions that have existing refills available in order to improve patient compliance with and adherence to prescribed medication therapy. The following is applicable in order to enroll patients into an auto-refill program:

(i) Notice of the availability of an auto-refill program shall be given to the patient or patient's agent, and the patient or patient's agent must affirmatively indicate that they wish to enroll in such a program and the pharmacy shall document such indication.

(ii) The patient or patient's agent shall have the option to withdraw from such a program at any time.

(iii) Auto-refill programs may be used for refills of dangerous drugs, and Schedules IV and V controlled substances. Schedules II and III controlled substances may not be dispensed by an auto-refill program.

(iv) As is required for all prescriptions, a drug regimen review shall be completed on all prescriptions filled as a result of the auto-refill program. Special attention shall be noted for drug regimen review warnings of duplication of therapy and all such conflicts shall be resolved with the prescribing practitioner prior to refilling the prescription.

(9) Records Relating to Dispensing Errors. If a dispensing error occurs, the following is applicable.

(A) Original prescription drug orders:

(i) shall not be destroyed and must be maintained in accordance with subsection (a) of this section; and

(ii) shall not be altered. Altering includes placing a label or any other item over any of the information on the prescription drug order (e.g., a dispensing tag or label that is affixed to back of a prescription drug order must not be affixed on top of another dispensing tag or label in such a manner as to obliterate the information relating to the error).

(B) Prescription drug order records maintained in a data processing system:

(i) shall not be deleted and must be maintained in accordance with subsection (a) of this section;

(ii) may be changed only in compliance with subsection (e)(2)(B) of this section; and

(iii) if the error involved incorrect data entry into the pharmacy's data processing system, this record must be either voided or cancelled in the data processing system, so that the incorrectly entered prescription drug order may not be dispensed, or the data processing system must be capable of maintaining an audit trail showing any changes made to the data in the system.

(10) Accelerated refills. In accordance with §562.0545 of the Act, a pharmacist may dispense up to a 90-day supply of a dangerous drug pursuant to a valid prescription that specifies the dispensing of a lesser amount followed by periodic refills of that amount if:

(A) the total quantity of dosage units dispensed does not exceed the total quantity of dosage units authorized by the prescriber on the original prescription, including refills;

(B) the patient consents to the dispensing of up to a 90-day supply and the physician has been notified electronically or by telephone;

(C) the physician has not specified on the prescription that dispensing the prescription in an initial amount followed by periodic refills is medically necessary;

(D) the dangerous drug is not a psychotropic drug used to treat mental or psychiatric conditions; and

(E) the patient is at least 18 years of age.

(c) Patient medication records.

(1) A patient medication record system shall be maintained by the pharmacy for patients to whom prescription drug orders are dispensed.

(2) The patient medication record system shall provide for the immediate retrieval of information for the previous 12 months that is necessary for the dispensing pharmacist to conduct a prospective drug regimen review at the time a prescription drug order is presented for dispensing.

(3) The pharmacist-in-charge shall assure that a reasonable effort is made to obtain and record in the patient medication record at least the following information:

(A) full name of the patient for whom the drug is prescribed;

(B) address and telephone number of the patient;

(C) patient's age or date of birth;

(D) patient's gender;

(E) any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other drugs currently being used by the patient which may relate to prospective drug regimen review;

(F) pharmacist's comments relevant to the individual's drug therapy, including any other information unique to the specific patient or drug; and

(G) a list of all prescription drug orders dispensed (new and refill) to the patient by the pharmacy during the last two years. Such lists shall contain the following information:

(i) date dispensed;

(ii) name, strength, and quantity of the drug dispensed;

(iii) prescribing practitioner's name;

(iv) unique identification number of the prescription; and

(v) name or initials of the dispensing pharmacists.

(4) A patient medication record shall be maintained in the pharmacy for two years. If patient medication records are maintained in a data processing system, all of the information specified in this subsection shall be maintained in a retrievable form for two years and information for the previous 12 months shall be maintained online. A patient medication record must contain documentation of any modification, change, or manipulation to a patient profile.

(5) Nothing in this subsection shall be construed as requiring a pharmacist to obtain, record, and maintain patient information other than prescription drug order information when a patient or patient's agent refuses to provide the necessary information for such patient medication records.

(d) Prescription drug order records maintained in a manual system.

(1) Original prescriptions shall be maintained in three files as specified in subsection (b)(6)(D) of this section.

(2) Refills.

(A) Each time a prescription drug order is refilled, a record of such refill shall be made:

(i) on the back of the prescription by recording the date of dispensing, the written initials or identification code of the dispensing pharmacist, the initials or identification code of the pharmacy technician or pharmacy technician trainee preparing the prescription label, if applicable, and the amount dispensed. (If the pharmacist merely initials and dates the back of the prescription drug order, he or she shall be deemed to have dispensed a refill for the full face amount of the prescription drug order); or

(ii) on another appropriate, uniformly maintained, readily retrievable record, such as medication records, that indicates by patient name the following information:

(I) unique identification number of the prescription;

(II) name and strength of the drug dispensed;

(III) date of each dispensing;

(IV) quantity dispensed at each dispensing;

(V) initials or identification code of the dispensing pharmacist;

(VI) initials or identification code of the pharmacy technician or pharmacy technician trainee preparing the prescription label, if applicable; and

(VII) total number of refills for the prescription.

(B) If refill records are maintained in accordance with subparagraph (A)(ii) of this paragraph, refill records for controlled substances in Schedules III-V shall be maintained separately from refill records of dangerous drugs and nonprescription drugs.

(3) Authorization of refills. Practitioner authorization for additional refills of a prescription drug order shall be noted on the original prescription, in addition to the documentation of dispensing the refill as specified in subsection (l) of this section.

(4) Each time a modification, change, or manipulation is made to a record of dispensing, documentation of such change shall be recorded on the back of the prescription or on another appropriate, uniformly maintained, readily retrievable record, such as medication records. The documentation of any modification, change, or manipulation to a record of dispensing shall include the identification of the individual responsible for the alteration.

(e) Prescription drug order records maintained in a data processing system.

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

(A) Compliance with data processing system requirements. If a Class A pharmacy's data processing system is not in compliance with this subsection, the pharmacy must maintain a manual record keeping system as specified in subsection (d) of this section.

(B) Original prescriptions. Original prescriptions shall be maintained in three files as specified in subsection (b)(6)(D) of this section.

(C) Requirements for backup systems.

(i) The pharmacy 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, at least monthly, to assure that data is not lost due to system failure.

(ii) Data processing systems shall have a workable (electronic) data retention system that can produce an audit trail of drug usage for the preceding two years as specified in paragraph (2)(H) of this subsection.

(D) Change or discontinuance of a data processing system.

(i) Records of dispensing. A pharmacy that changes or discontinues use of a data processing system must:

(I) transfer the records of dispensing to the new data processing system; or

(II) purge the records of dispensing to a printout that contains the same information required on the daily printout as specified in paragraph (2)(C) of this subsection. The information on this hard copy printout shall be sorted and printed by prescription number and list each dispensing for this prescription chronologically.

(ii) Other records. 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 that contains all of the information required on the original document.

(iii) Maintenance of purged records. 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) Loss of data. 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.

(2) Records of dispensing.

(A) Each time a prescription drug order is filled or refilled, a record of such dispensing shall be entered into the data processing system.

(B) Each time a modification, change or manipulation is made to a record of dispensing, documentation of such change shall be recorded in the data processing system. The documentation of any modification, change, or manipulation to a record of dispensing shall include the identification of the individual responsible for the alteration. Should the data processing system not be able to record a modification, change, or manipulation to a record of dispensing, the information should be clearly documented on the hard copy prescription.

(C) The data processing system shall have the capacity to produce a daily hard copy printout of all original prescriptions dispensed and refilled. This hard copy printout shall contain the following information:

(i) unique identification number of the prescription;

(ii) date of dispensing;

(iii) patient name;

(iv) prescribing practitioner's name and the supervising physician's name if the prescription was issued by an advanced practice registered nurse, physician assistant or pharmacist;

(v) name and strength of the drug product actually dispensed; if generic name, the brand name or manufacturer of drug dispensed;

(vi) quantity dispensed;

(vii) initials or an identification code of the dispensing pharmacist;

(viii) initials or an identification code of the pharmacy technician or pharmacy technician trainee performing data entry of the prescription, if applicable;

(ix) if not immediately retrievable via computer display, the following shall also be included on the hard copy printout:

(I) patient's address;

(II) prescribing practitioner's address;

(III) practitioner's DEA registration number, if the prescription drug order is for a controlled substance;

(IV) quantity prescribed, if different from the quantity dispensed;

(V) date of issuance of the prescription drug order, if different from the date of dispensing; and

(VI) total number of refills dispensed to date for that prescription drug order; and

(x) any changes made to a record of dispensing.

(D) The daily hard copy printout shall be produced within 72 hours of the date on which the prescription drug orders were dispensed and shall be maintained in a separate file at the pharmacy. Records of controlled substances shall be readily retrievable from records of non-controlled substances.

(E) Each individual pharmacist who dispenses or refills a prescription drug order shall verify that the data indicated on the daily hard copy printout is correct, by dating and signing such document in the same manner as signing a check or legal document (e.g., J.H. Smith, or John H. Smith) within seven days from the date of dispensing.

(F) In lieu of the printout described in subparagraph (C) of this paragraph, the pharmacy shall maintain a log book in which each individual pharmacist using the data processing system shall sign or electronically sign a statement each day, attesting to the fact that the information entered into the data processing system that day has been reviewed by him or her and is correct as entered. Such log book shall be maintained at the pharmacy employing such a system for a period of two years after the date of dispensing; provided, however, that the data processing system can produce the hard copy printout on demand by an authorized agent of the Texas State Board of Pharmacy. If no printer is available on site, the hard copy printout shall be available within 72 hours with a certification by the individual providing the printout, stating that the printout is true and correct as of the date of entry and such information has not been altered, amended, or modified.

(G) The pharmacist-in-charge is responsible for the proper maintenance of such records, for ensuring that such data processing system can produce the records outlined in this section, and that such system is in compliance with this subsection.

(H) The data processing system shall be capable of producing a hard copy printout of an audit trail for all dispensing (original and refill) of any specified strength and dosage form of a drug (by either brand or generic name or both) during a specified time period.

(i) Such audit trail shall contain all of the information required on the daily printout as set out in subparagraph (C) of this paragraph.

(ii) The audit trail required in this subparagraph shall be supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy.

(I) 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.

(J) The data processing system shall provide online retrieval (via computer display or hard copy printout) of the information set out in subparagraph (C) of this paragraph of:

(i) the original controlled substance prescription drug orders currently authorized for refilling; and

(ii) the current refill history for Schedules III, IV, and V controlled substances for the immediately preceding six-month period.

(K) In the event that a pharmacy using a data processing system experiences system downtime, the following is applicable:

(i) an auxiliary procedure shall ensure that refills are authorized by the original prescription drug order and that the maximum number of refills has not been exceeded, or authorization from the prescribing practitioner shall be obtained prior to dispensing a refill; and

(ii) all of the appropriate data shall be retained for online data entry as soon as the system is available for use again.

(3) Authorization of refills. Practitioner authorization for additional refills of a prescription drug order shall be noted as follows:

(A) on the hard copy prescription drug order;

(B) on the daily hard copy printout; or

(C) via the computer display.

(f) Limitation to one type of recordkeeping system. When filing prescription drug order information a pharmacy may use only one of the two systems described in subsection (d) or (e) of this section.

(g) Transfer of prescription drug order information. For the purpose of initial or refill dispensing, the transfer of original prescription drug order information is permissible between pharmacies, subject to the following requirements:

(1) The transfer of original prescription drug order information for controlled substances listed in Schedules III, IV, or V for the purpose of refill dispensing is permissible between pharmacies on a one-time basis only. However, pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization.

(2) The transfer of original prescription drug order information for dangerous drugs is permissible between pharmacies without limitation up to the number of originally authorized refills.

(3) The transfer is communicated orally by telephone or via facsimile:

(A) directly by a pharmacist or pharmacist-intern to another pharmacist or pharmacist-intern for prescription drug order information for controlled substances; or

(B) directly by a pharmacist, pharmacist-intern, or pharmacy technician to another pharmacist, pharmacist-intern, or pharmacy technician for prescription drug order information for dangerous drugs.

(4) Both the original and the transferred prescription drug orders are maintained for a period of two years from the date of last refill.

(5) The individual transferring the prescription drug order information shall:

(A) write the word "void" on the face of the invalidated prescription or the prescription is voided in the data processing system;

(B) record the name, address, and if for a controlled substance, the DEA registration number of the pharmacy to which it was transferred, and the name of the receiving individual on the reverse of the invalidated prescription or stored with the invalidated prescription drug order in the data processing system;

(C) record the date of the transfer and the name of the individual transferring the information; and

(D) if the prescription is transferred electronically, provide the following information:

(i) date of original dispensing and prescription number;

(ii) number of refills remaining and if a controlled substance, the date(s) and location(s) of previous refills;

(iii) name, address, and if a controlled substance, the DEA registration number of the transferring pharmacy;

(iv) name of the individual transferring the prescription; and

(v) if a controlled substance, the name, address, DEA registration number, and prescription number from the pharmacy that originally dispensed the prescription, if different.

(6) The individual receiving the transferred prescription drug order information shall:

(A) write the word "transfer" on the face of the prescription or indicate in the prescription record that the prescription was a transfer; and

(B) reduce to writing all of the information required to be on a prescription as specified in subsection (b)(7) of this section [~~(relating to Prescriptions)~~], and the following:

(i) date of issuance and prescription number;

(ii) original number of refills authorized on the original prescription drug order;

(iii) date of original dispensing;

(iv) number of valid refills remaining, and if a controlled substance, the date(s) and location(s) of previous refills;

(v) name, address, and if for a controlled substance, the DEA registration number of the transferring pharmacy;

(vi) name of the individual transferring the prescription; and

(vii) name, address, and if for a controlled substance, the DEA registration number, of the pharmacy that originally dispensed the prescription, if different; or

(C) if the prescription is transferred electronically, create an electronic record for the prescription that includes the receiving pharmacist's name and all of the information transferred with the prescription including all of the information required to be on a prescription as specified in subsection (b)(7) of this section [~~(relating to Prescriptions)~~], and the following:

(i) date of original dispensing;

(ii) number of refills remaining and if a controlled substance, the prescription number(s), date(s) and location(s) of previous refills;

(iii) name, address, and if for a controlled substance, the DEA registration number;

(iv) name of the individual transferring the prescription; and

(v) name, address, and if for a controlled substance, the DEA registration number, of the pharmacy that originally filled the prescription.

(7) Both the individual transferring the prescription and the individual receiving the prescription must engage in confirmation of the prescription information by such means as:

(A) the transferring individual faxes the hard copy prescription to the receiving individual; or

(B) the receiving individual repeats the verbal information from the transferring individual and the transferring individual verbally confirms that the repeated information is correct.

(8) Pharmacies transferring prescriptions electronically shall comply with the following:

(A) Prescription drug orders may not be transferred by non-electronic means during periods of downtime except on consultation with and authorization by a prescribing practitioner; provided, however, that during downtime, a hard copy of a prescription drug order may be made available for informational purposes only, to the patient or a pharmacist, and the prescription may be read to a pharmacist by telephone;

(B) The original prescription drug order shall be invalidated in the data processing system for purposes of filling or refilling, but shall be maintained in the data processing system for refill history purposes;

(C) If the data processing system does not have the capacity to store all the information as specified in paragraphs (5) and (6) of this subsection, the pharmacist is required to record this information on the original or transferred prescription drug order;

(D) The data processing system shall have a mechanism to prohibit the transfer or refilling of controlled substance prescription drug orders that have been previously transferred; and

(E) Pharmacies electronically accessing the same prescription drug order records may electronically transfer prescription information if the following requirements are met:

(i) The original prescription is voided and the pharmacies' data processing systems store all the information as specified in paragraphs (5) and (6) of this subsection;

(ii) Pharmacies not owned by the same entity may electronically access the same prescription drug order records, provided the owner, chief executive officer, or designee of each pharmacy signs an agreement allowing access to such prescription drug order records; and

(iii) An electronic transfer between pharmacies may be initiated by a pharmacist intern, pharmacy technician, or pharmacy technician trainee acting under the direct supervision of a pharmacist.

(9) An individual may not refuse to transfer original prescription information to another individual who is acting on behalf of a patient and who is making a request for this information as specified in this subsection. The transfer of original prescription information must be completed within four business hours of the request.

(10) When transferring a compounded prescription, a pharmacy is required to provide all of the information regarding the

compounded preparation, including the formula, unless the formula is patented or otherwise protected, in which case, the transferring pharmacy shall, at a minimum, provide the quantity or strength of all of the active ingredients of the compounded preparation.

(11) The electronic transfer of multiple or bulk prescription records between two pharmacies is permitted provided:

(A) a record of the transfer as specified in paragraph (5) of this subsection is maintained by the transferring pharmacy;

(B) the information specified in paragraph (6) of this subsection is maintained by the receiving pharmacy; and

(C) in the event that the patient or patient's agent is unaware of the transfer of the prescription drug order record, the transferring pharmacy must notify the patient or patient's agent of the transfer and must provide the patient or patient's agent with the telephone number of the pharmacy receiving the multiple or bulk prescription drug order records.

(h) 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.

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

(2) The total number of dosage units of controlled substances distributed by a pharmacy may not exceed 5.0% of all controlled substances dispensed and distributed 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.

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

(A) the actual date of distribution;

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

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

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

(4) A pharmacy shall comply with 21 CFR 1305 regarding the DEA order form (DEA 222) requirements when distributing a Schedule II controlled substance. [~~If the distribution is for a Schedule II controlled substance, the following is applicable:~~]

~~(A) The pharmacy, practitioner, or other registrant who is receiving the controlled substances shall issue Copy 1 and Copy 2 of a DEA order form (DEA 222) to the distributing pharmacy; and~~

~~(B) The distributing pharmacy shall:~~

~~*(i)* complete the area on the DEA order form (DEA 222) titled "To Be Filled in by Supplier";~~

~~*(ii)* maintain Copy 1 of the DEA order form (DEA 222) at the pharmacy for two years; and~~

~~*(iii)* forward Copy 2 of the DEA order form (DEA 222) to the Divisional Office of the Drug Enforcement Administration.~~

(i) Other records. Other records to be maintained by a pharmacy:

(1) a log of the initials or identification codes that will identify each pharmacist, pharmacy technician, and pharmacy technician trainee who is involved in the dispensing process, in the pharmacy's data processing system (the initials or identification code shall be unique to ensure that each individual can be identified, i.e., identical initials or identification codes shall not be used). Such log shall be maintained at the pharmacy for at least seven years from the date of the transaction;

[~~(2) copy 3 of DEA order forms (DEA 222) that have been properly dated, initialed, and filed, all copies of each unaccepted or defective order form and any attached statements or other documents, and/or for each order filled using the DEA Controlled Substance Ordering System (CSOS), the original signed order and all linked records for that order;~~]

[~~(3) a copy of the power of attorney to sign DEA 222 order forms (if applicable);~~]

(2) [~~(4)~~] suppliers' invoices of dangerous drugs and controlled substances; a pharmacist shall verify that the controlled substances listed on the invoices were actually received by clearly recording his/her initials and the actual date of receipt of the controlled substances;

(3) [~~(5)~~] suppliers' credit memos for controlled substances and dangerous drugs;

(4) [~~(6)~~] a copy of inventories required by §291.17 of this title (relating to Inventory Requirements);

(5) [~~(7)~~] reports of surrender or destruction of controlled substances and/or dangerous drugs to an appropriate state or federal agency;

(6) [~~(8)~~] records of distribution of controlled substances and/or dangerous drugs to other pharmacies, practitioners, or registrants; and

(7) [~~(9)~~] a copy of any notification required by the Texas Pharmacy Act or the sections in this chapter, including, but not limited to, the following:

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

(B) notifications of a change in pharmacist-in-charge of a pharmacy; and

(C) reports of a fire or other disaster that 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.

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

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

(A) Prior to the initiation of central recordkeeping, the pharmacy submits written notification by registered or certified mail to the divisional director of the Drug Enforcement Administration as required by Title 21, Code of Federal Regulations, §1304.04(a), and submits a copy of this written notification to the board. Unless the registrant is informed by the divisional director of the Drug Enforcement Administration 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;

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

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

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

(3) 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; and

(4) 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.

(k) Ownership of pharmacy records. For the purposes of these sections, a pharmacy licensed under the Act is the only entity that may legally own and maintain prescription drug records.

(l) Documentation of consultation. When a pharmacist, pharmacist-intern, or pharmacy technician consults a prescriber as described in this section, the individual shall document such occurrences on the hard copy or in the pharmacy's data processing system associated with the prescription and shall include the following information:

(1) date the prescriber was consulted;

(2) name of the person communicating the prescriber's instructions;

(3) any applicable information pertaining to the consultation; and

(4) initials or identification code of the pharmacist, pharmacist-intern, or pharmacy technician performing the consultation clearly recorded for the purpose of identifying the individual who performed the consultation if the information is recorded on the hard copy prescription.

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

Filed with the Office of the Secretary of State on March 15, 2021.

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Allison Vordenbaumen Benz, R.Ph., M.S.
Executive Director
Texas State Board of Pharmacy
Earliest possible date of adoption: May 2, 2021
For further information, please call: (512) 305-8010

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SUBCHAPTER D. INSTITUTIONAL PHARMACY (CLASS C)

22 TAC §291.75

The Texas State Board of Pharmacy proposes amendments to §291.75, concerning Records. The amendments, if adopted, will update references to DEA 222 form requirements to be consistent with federal regulations.

Allison Vordenbaumen Benz, R.Ph., M.S., Executive Director/Secretary, has determined that, for the first five-year period the rules are in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule. Ms. Benz has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the amendments will be to ensure consistency between Board rules and federal regulations. There is no anticipated adverse economic impact on large, small or micro-businesses (pharmacies), rural communities, or local or state employment. Therefore, an economic impact statement and regulatory flexibility analysis are not required.

For each year of the first five years the proposed amendments will be in effect, Ms. Benz has determined the following:

(1) The proposed amendments do not create or eliminate a government program;

(2) Implementation of the proposed amendments does not require the creation of new employee positions or the elimination of existing employee positions;

(3) Implementation of the proposed amendments does not require an increase or decrease in the future legislative appropriations to the agency;

(4) The proposed amendments do not require an increase or decrease in fees paid to the agency;

(5) The proposed amendments do not create a new regulation;

(6) The proposed amendments do not limit or expand an existing regulation;

(7) The proposed amendments do not increase or decrease the number of individuals subject to the rule's applicability; and

(8) The proposed amendments do not positively or adversely affect this state's economy.

Written comments on the amendments may be submitted to Megan G. Holloway, Deputy General Counsel, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-500, Austin, Texas, 78701, FAX (512) 305-8061. Comments must be received by 5:00 p.m., May 4, 2021.

The amendments are proposed 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 these amendments: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

§291.75. Records.

(a) Maintenance of records.

(1) Every inventory or other record required to be kept under the provisions of §291.71 of this title (relating to Purpose), §291.72 of this title (relating to Definitions), §291.73 of this title (relating to Personnel), §291.74 of this title (relating to Operational Standards), and this section contained in Institutional Pharmacy (Class C) shall be:

(A) kept by the institutional 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

(B) 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.

(2) Records of controlled substances listed in Schedules I and II shall be maintained separately from all other records of the pharmacy.

(3) 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 subsection, 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.

(4) 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:

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

(B) 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.

(b) Outpatient records.

(1) Outpatient records shall be maintained as provided in §291.34 (relating to Records), and §291.35 (relating to Official Prescription Requirements), in chapter 291, subchapter B of this title.

(2) Outpatient prescriptions, including, but not limited to, furlough and discharge prescriptions, that are written by a practitioner must be written on a form which meets the requirements of §291.34(b)(7)(A) of this title. Medication order forms or copies thereof do not meet the requirements for outpatient forms.

(3) Controlled substances listed in Schedule II must be written on an official prescription form in accordance with the Texas Controlled Substances Act, §481.075, and rules promulgated pursuant to the Texas Controlled Substances Act, unless exempted by chapter 315 of this title (relating to Controlled Substances). Outpatient prescriptions for Schedule II controlled substances that are exempted from the official prescription requirement must be manually signed by the practitioner.

(c) Patient records.

(1) Original medication orders.

(A) Each original medication order shall bear the following information:

(i) patient name and room number or identification number;

(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.

(B) Original medication orders shall be maintained with the medication administration records of the patients.

(2) Patient medication records (PMR). A patient medication record shall be maintained for each patient of the facility. The PMR shall contain at a minimum the following information:

(A) Patient information:

(i) patient name and room number or identification number;

(ii) gender, and date of birth or age;

(iii) weight and height;

(iv) known drug sensitivities and allergies to drugs and/or food;

(v) primary diagnoses and chronic conditions;

(vi) primary physician; and

(vii) other drugs the patient is receiving; and

(B) Medication order information:

(i) date of distribution;

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

(iii) directions for use.

(3) Controlled substances records. Controlled substances records shall be maintained as follows:

(A) All records for controlled substances shall be maintained in a readily retrievable manner; and

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

(4) Schedule II controlled substances records. Records of controlled substances listed in Schedule II shall be maintained as follows:

(A) Records of controlled substances listed in Schedule II shall be maintained separately from records of controlled substances in Schedules III, IV, and V, and all other records;

(B) An institutional pharmacy shall maintain a perpetual inventory of any controlled substance listed in Schedule II; and

(C) Distribution records for controlled substances listed in Schedule II shall bear the following information:

(i) patient's name;

(ii) prescribing or attending practitioner;

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

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

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

(vi) returns to the pharmacy; and

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

(5) Floor stock records.

(A) Distribution records for Schedules II - V controlled substances floor stock shall include the following information:

(i) patient's name;

(ii) prescribing or attending practitioner;

(iii) name of controlled substance, dosage form, and strength;

(iv) time and date of administration to patient;

(v) quantity administered;

(vi) name, initials, or electronic signature of the individual administering drug;

(vii) returns to the pharmacy; and

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

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

(C) A pharmacist shall review distribution records with medication orders on a periodic basis to verify proper usage of drugs, not to exceed 30 days between such reviews.

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

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

(B) Requirements for backup systems. 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, at least monthly, to assure that data is not lost due to system failure.

(C) Change or discontinuance of a data processing system.

(i) Records of distribution and return for all controlled substances. 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 the same information as required on the audit trail printout as specified in paragraph (7)(B) of this subsection. The information on this printout shall be sorted and printed by drug name and list all distributions/returns chronologically.

(ii) Other records. 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 all of the information required on the original document.

(iii) Maintenance of purged records. 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.

(D) Loss of data. 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.

(7) Data processing system maintenance of records for the distribution and return of all controlled substances to the pharmacy.

(A) Each time a controlled substance is distributed from or returned to the pharmacy, a record of such distribution or return shall be entered into the data processing system.

(B) 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.

(C) 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 unless the pharmacy complies with subparagraph (D) of this paragraph. The information on this printout shall be sorted by drug name and list all distributions/returns for that drug chronologically.

(D) 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 paragraph 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.

(8) Failure to maintain records. Failure to provide records set out in this subsection, either on site or within 72 hours for whatever reason, constitutes prima facie evidence of failure to keep and maintain records.

(9) Data processing system downtime. In the event that a hospital pharmacy that uses a data processing system experiences system downtime, the pharmacy must have an auxiliary procedure which will ensure that all data is retained for on-line data entry as soon as the system is available for use again.

(10) Ongoing clinical pharmacy program records. If a pharmacy has an ongoing clinical pharmacy program and allows pharmacy technicians to verify the accuracy of work performed by other pharmacy technicians, the pharmacy must have a record of the pharmacy technicians and the duties performed.

(d) 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:

(1) The registrant to whom the controlled substance is to be distributed is registered under the Controlled Substances Act to dispense that controlled substance; and

(2) The total number of dosage units of controlled substances distributed by a pharmacy may not exceed 5.0% of all controlled substances dispensed or distributed 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.

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

(A) the actual date of distribution;

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

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

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

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

[~~(4) If the distribution is for a Schedule I or II controlled substance, the following is applicable:~~]

[~~(A) The pharmacy, practitioner or other registrant who is receiving the controlled substances shall issue copy 1 and copy 2 of a DEA order form (DEA 222) to the distributing pharmacy; and~~]

[~~(B) The distributing pharmacy shall:~~]

~~*(i)* complete the area on the DEA order form (DEA 222) titled TO BE FILLED IN BY SUPPLIER;~~]

~~*(ii)* maintain copy 1 of the DEA order form (DEA 222) at the pharmacy for two years; and~~]

~~*(iii)* forward copy 2 of the DEA order form (DEA 222) to the divisional office of the Drug Enforcement Administration.~~]

(e) Other records. Other records to be maintained by a pharmacy:

(1) a log of the initials or identification codes which identifies pharmacy personnel by name. The initials or identification code shall be unique to ensure that each person 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;

[~~(2) copy 3 of DEA order forms (DEA 222) which have been properly dated, initialed, and filed, and all copies of each unaccepted or defective order form and any attached statements or other documents;~~]

[~~(3) a hard copy of the power of attorney to sign DEA 222 order forms (if applicable);~~]

(2) [~~(4)~~] suppliers' invoices of dangerous drugs and controlled substances; a pharmacist shall verify that the controlled drugs listed on the invoices were actually received by clearly recording his/her initials and the actual date of receipt of the controlled substances;

(3) [~~(5)~~] suppliers' credit memos for controlled substances and dangerous drugs;

(4) [~~(6)~~] a hard 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;

(5) [~~(7)~~] hard copy reports of surrender or destruction of controlled substances and/or dangerous drugs to an appropriate state or federal agency;

(6) [~~(8)~~] a hard copy Schedule V nonprescription register book;

(7) [~~(9)~~] records of distribution of controlled substances and/or dangerous drugs to other pharmacies, practitioners, or registrants; and

(8) [~~(10)~~] a hard copy of any notification required by the Texas Pharmacy Act or these sections including, but not limited to, the following:

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

(B) notifications of a change in pharmacist-in-charge of a pharmacy; and

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

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

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

(A) 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 Title 21, Code of Federal Regulations, §1304.04(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;

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

(C) 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.

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

(3) 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.

(4) 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 proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on March 15, 2021.

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Executive Director
Texas State Board of Pharmacy
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For further information, please call: (512) 305-8010

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22 TAC §291.76

The Texas State Board of Pharmacy proposes amendments to §291.76, concerning Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center. The amendments, if adopted, update references to DEA 222 form requirements to be consistent with federal regulations.

Allison Vordenbaumen Benz, R.Ph., M.S., Executive Director/Secretary, has determined that, for the first five-year period the rules are in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule. Ms. Benz has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the amendments will be to ensure consistency between Board rules and federal regulations. There is no anticipated adverse economic impact on large, small or micro-businesses (pharmacies), rural communities, or local or state employment. Therefore, an economic impact statement and regulatory flexibility analysis are not required.

For each year of the first five years the proposed amendments will be in effect, Ms. Benz has determined the following:

(1) The proposed amendments do not create or eliminate a government program;

(2) Implementation of the proposed amendments does not require the creation of new employee positions or the elimination of existing employee positions;

(3) Implementation of the proposed amendments does not require an increase or decrease in the future legislative appropriations to the agency;

(4) The proposed amendments do not require an increase or decrease in fees paid to the agency;

(5) The proposed amendments do not create a new regulation;

(6) The proposed amendments do not limit or expand an existing regulation;

(7) The proposed amendments do not increase or decrease the number of individuals subject to the rule's applicability; and

(8) The proposed amendments do not positively or adversely affect this state's economy.

Written comments on the amendments may be submitted to Megan G. Holloway, Deputy General Counsel, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-500, Austin, Texas, 78701, FAX (512) 305-8061. Comments must be received by 5:00 p.m., May 4, 2021.

The amendments are proposed 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 these amendments: 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 prepacker;

(-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 or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist. 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 taken;

(V) time and date; and

(VI) signature or electronic signature of person making 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 as soon as practical, but in no event more than 72 hours from the time of such withdrawal.

(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; and

(iii) The pharmacist shall conduct an audit of the patient's medical record according to the schedule set out in the policy and procedures at a reasonable interval, but such interval 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 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; 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) A pharmacist shall verify the withdrawal according to the following schedule.

(i) In facilities with a full-time pharmacist, the withdrawal shall be verified as soon as practical, but in no event more than 72 hours from the time of such withdrawal.

(ii) In facilities with a part-time or consultant pharmacist, the withdrawal shall be verified after a reasonable interval, but such interval must occur at least once in every calendar week that the pharmacy is open.

(iii) 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.

(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. [~~If the distribution is for a Schedule II controlled substance, the following is applicable.~~]

~~*[(i)* The pharmacy, practitioner, or other registrant who is receiving the controlled substances shall issue Copy 1 and Copy 2 of a DEA order form (DEA 222) to the distributing pharmacy.]~~

~~*[(ii)* The distributing pharmacy shall:]~~

~~*[(I)* complete the area on the DEA order form (DEA 222) titled "To Be Filled in by Supplier";]~~

~~*[(II)* maintain Copy 1 of the DEA order form (DEA 222) at the pharmacy for two years; and]~~

~~*[(III)* forward Copy 2 of the DEA order form (DEA 222) to the divisional office of DEA.]~~

(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) Copy 3 of DEA order forms (DEA 222), which have been properly dated, initialed, and filed, and all copies of each unaccepted or defective order form and any attached statements or other documents and/or for each order filled using the DEA Controlled Substance Ordering System (CSOS), the original signed order and all linked records for that order;]~~

~~[(C) a copy of the power of attorney to sign DEA 222 order forms (if applicable);]~~

(B) [~~(D)~~] suppliers' invoices of dangerous drugs and controlled substances dated and initialed or signed by the person receiving the drugs; a pharmacist shall verify that the controlled drugs 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;

(C) [~~(E)~~] supplier's credit memos for controlled substances and dangerous drugs;

(D) [~~(F)~~] 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) [~~(G)~~] reports of surrender or destruction of controlled substances and/or dangerous drugs to an appropriate state or federal agency;

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

(G) [~~(I)~~] 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 proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on March 15, 2021.

TRD-202101091
Allison Vordenbaumen Benz, R.Ph., M.S.
Executive Director
Texas State Board of Pharmacy
Earliest possible date of adoption: May 2, 2021
For further information, please call: (512) 305-8010

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CHAPTER 315. CONTROLLED SUBSTANCES

22 TAC §315.3

The Texas State Board of Pharmacy proposes amendments to §315.3 concerning Prescriptions. The amendments, if adopted, extend the time period for Schedule II prescriptions to be valid to no longer than 30 days to be consistent with federal law.

Allison Vordenbaumen Benz, R.Ph., M.S., Executive Director/Secretary, has determined that, for the first five-year period the rules are in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule. Ms. Benz has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the amendments will be to provide consistency between Board rules and federal law. There is no anticipated adverse economic impact on large, small or micro-businesses (pharmacies), rural communities, or local or state employment. Therefore, an economic impact statement and regulatory flexibility analysis are not required.

For each year of the first five years the proposed amendments will be in effect, Ms. Benz has determined the following:

(1) The proposed amendments do not create or eliminate a government program;

(2) Implementation of the proposed amendments does not require the creation of new employee positions or the elimination of existing employee positions;

(3) Implementation of the proposed amendments does not require an increase or decrease in the future legislative appropriations to the agency;

(4) The proposed amendments do not require an increase or decrease in fees paid to the agency;

(5) The proposed amendments do not create a new regulation;

(6) The proposed amendments do limit an existing regulation in order to be consistent with federal law;

(7) The proposed amendments do not increase or decrease the number of individuals subject to the rule's applicability; and

(8) The proposed amendments do not positively or adversely affect this state's economy.

Written comments on the amendments may be submitted to Megan G. Holloway, Deputy General Counsel, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-500, Austin, Texas 78701 FAX (512) 305-8061. Comments must be received by 5:00 p.m., May 4, 2021.

The amendments are proposed 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 these amendments: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

§315.3. Prescriptions.

(a) Schedule II Prescriptions.

(1) Except as provided by subsection (e) of this section, a practitioner, as defined in §481.002(39)(A) of the TCSA, must issue a written prescription for a Schedule II controlled substance only on an official Texas prescription form or through an electronic prescription that meets all requirements of the TCSA. This subsection also applies to a prescription issued in an emergency situation.

(2) A practitioner who issues a written prescription for any quantity of a Schedule II controlled substance must complete an official prescription form.

(3) Except as provided by subsection (f) of this section, a practitioner may issue multiple written prescriptions authorizing a patient to receive up to a 90-day supply of a Schedule II controlled substance provided:

(A) each prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice;

(B) the practitioner provides written instructions on each prescription, other than the first prescription if the practitioner intends for that prescription to be filled immediately, indicating the earliest date on which a pharmacy may dispense each prescription; and

(C) the practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse.

(4) A schedule II prescription must be dispensed no later than 30 [~~21~~] days after the date of issuance or, if the prescription is part of a multiple set of prescriptions, issued on the same day, no later than 30 [~~21~~] days after the earliest date on which a pharmacy may dispense the prescription as indicated on each prescription.

(5) A person dispensing a Schedule II controlled substance prescription shall provide written notice on the safe disposal of controlled substance prescription drugs that includes information on loca-

tions at which Schedule II controlled substance prescription drugs are accepted for safe disposal. In lieu of listing those locations, the notice may alternatively provide the address of an Internet website specified by the board that provides a searchable database of locations at which Schedule II controlled substance prescription drugs are accepted for safe disposal. The written notice may be provided to the patient in an electronic format, such as by e-mail, if the patient or patient's agent requests the notice in an electronic format and the request is documented. Such written notice is not required if:

(A) the Schedule II controlled substance prescription drug is dispensed at a pharmacy or other location that:

(i) is authorized to take back those drugs for safe disposal; and

(ii) regularly accepts those drugs for safe disposal; or

(B) the dispenser provides to the person to whom the Schedule II controlled substance prescription drug is dispensed, at the time of dispensation and at no cost to the person:

(i) a mail-in pouch for surrendering unused controlled substance prescription drugs; or

(ii) chemicals to render any unused drugs unusable or non-retrievable.

(b) Schedules III through V Prescriptions.

(1) A practitioner, as defined in §§481.002(39)(A), (C), (D) of the TCSA, may use prescription forms and order forms through individual sources. A practitioner may issue, or allow to be issued by a person under the practitioner's direction or supervision, a Schedule III through V controlled substance on a prescription form for a valid medical purpose and in the course of medical practice.

(2) Except as provided in subsection (f) of this section, Schedule III through V prescriptions may be refilled up to five times within six months after date of issuance.

(c) Electronic prescribing.

(1) A practitioner is permitted to issue and to dispense an electronic controlled substance prescription only in accordance with the requirements of the Code of Federal Regulations, Title 21, Part 1311.

(2) Effective January 1, 2021, a prescription for a controlled substance is not required to be issued electronically and may be issued in writing if the prescription is issued:

(A) in circumstances in which electronic prescribing is not available due to temporary technological or electronic failure;

(B) by a practitioner to be dispensed by a pharmacy located outside this state; or

(C) in any other circumstance described in §481.0755(a) of the TCSA.

(3) A prescriber may apply for a waiver from the electronic prescribing requirement by:

(A) submitting a waiver request form to the agency that issued the license, certification, or registration to the prescriber, including any information requested on the form; and

(B) demonstrating circumstances necessitating a waiver from the requirement, including:

(i) economic hardship, as determined by the agency that issued the license, registration, or certification to the prescriber on a prescriber/by prescriber basis, taking into account factors including:

(I) any special situational factors affecting either the cost of compliance or ability to comply;

(II) the likely impact of compliance on profitability or viability; and

(III) the availability of measures that would mitigate the economic impact of compliance;

(ii) technological limitations not reasonably within the control of the prescriber; or

(iii) other exceptional circumstances demonstrated by the prescriber.

(C) A waiver may be issued to a prescriber for a period of one year as specified in Chapter 481 of the Texas Controlled Substances Act. A prescriber may reapply for a subsequent waiver not earlier than the 30th day before the date the waiver expires if the circumstances that necessitated the waiver continue.

(d) Controlled substance prescriptions may not be postdated.

(e) Advanced practice registered nurses or physician assistants may only use the official prescription forms issued with their name, address, phone number, and DEA numbers, and the delegating physician's name and DEA number.

(f) Opioids for the treatment of acute pain.

(1) For the treatment of acute pain, as defined in §481.07636 of the TCSA, a practitioner may not:

(A) issue a prescription for an opioid in an amount that exceeds a 10-day supply; or

(B) provide for a refill of the opioid prescription.

(2) Paragraph (1) of this subsection does not apply to a prescription for an opioid approved by the U.S. Food and Drug Administration for the treatment of substance addiction that is issued by a practitioner for the treatment of substance addiction.

(3) A dispenser is not subject to criminal, civil, or administrative penalties for dispensing or refusing to dispense a controlled substance under a prescription that exceed the limits provided by paragraph (1) of this subsection.

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

Filed with the Office of the Secretary of State on March 15, 2021.

TRD-202101092
Allison Vordenbaumen Benz, R.Ph., M.S.
Executive Director
Texas State Board of Pharmacy
Earliest possible date of adoption: May 2, 2021
For further information, please call: (512) 305-8010

22 TAC §315.5

The Texas State Board of Pharmacy proposes amendments to §315.5, concerning Pharmacy Responsibility - Generally - Effective September 1, 2016. The amendments, if adopted, remove the effective date from the short title and extend the time period

for Schedule II prescriptions to be valid to no longer than 30 days to be consistent with federal law.

Allison Vordenbaumen Benz, R.Ph., M.S., Executive Director/Secretary, has determined that, for the first five-year period the rules are in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule. Ms. Benz has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the amendments will be to provide clearer regulatory language and consistency between Board rules and federal law. There is no anticipated adverse economic impact on large, small or micro-businesses (pharmacies), rural communities, or local or state employment. Therefore, an economic impact statement and regulatory flexibility analysis are not required.

For each year of the first five years the proposed amendments will be in effect, Ms. Benz has determined the following:

(1) The proposed amendments do not create or eliminate a government program;

(2) Implementation of the proposed amendments does not require the creation of new employee positions or the elimination of existing employee positions;

(3) Implementation of the proposed amendments does not require an increase or decrease in the future legislative appropriations to the agency;

(4) The proposed amendments do not require an increase or decrease in fees paid to the agency;

(5) The proposed amendments do not create a new regulation;

(6) The proposed amendments do limit an existing regulation in order to be consistent with federal law;

(7) The proposed amendments do not increase or decrease the number of individuals subject to the rule's applicability; and

(8) The proposed amendments do not positively or adversely affect this state's economy.

Written comments on the amendments may be submitted to Megan G. Holloway, Deputy General Counsel, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-500, Austin, Texas, 78701, FAX (512) 305-8061. Comments must be received by 5:00 p.m., May 4, 2021.

The amendments are proposed 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 these amendments: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

§315.5. Pharmacy Responsibility - Generally [- ~~Effective~~ ~~September 1, 2016~~].

(a) Upon receipt of a properly completed prescription form, a dispensing pharmacist must:

(1) if the prescription is for a Schedule II controlled substance, ensure the date the prescription is presented is not later than 30 [~~21~~] days after the date of issuance;

(2) if multiple prescriptions are issued by the prescribing practitioner allowing up to a 90-day supply of Schedule II controlled substances, ensure each prescription is neither dispensed prior to the earliest date intended by the practitioner nor dispensed beyond 30 [~~21~~] days from the earliest date the prescription may be dispensed;

(3) record the date dispensed and the pharmacy prescription number;

(4) indicate whether the pharmacy dispensed to the patient a quantity less than the quantity prescribed; and

(5) if issued on an official prescription form, record the following information, if different from the prescribing practitioner's information:

(A) the brand name or, if none, the generic name of the controlled substance dispensed; or

(B) the strength, quantity, and dosage form of the Schedule II controlled substance used to prepare the mixture or compound.

(b) The prescription presented for dispensing is void, and a new prescription is required, if:

(1) the prescription is for a Schedule II controlled substance, 30 [~~21~~] days after issuance, or 30 [~~21~~] days after any earliest dispense date; or

(2) the prescription is for a Schedule III, IV, or V controlled substance, more than six months after issuance or has been dispensed five times during the six months after issuance.

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

Filed with the Office of the Secretary of State on March 15, 2021.

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Allison Vordenbaumen Benz, R.Ph., M.S.
Executive Director
Texas State Board of Pharmacy
Earliest possible date of adoption: May 2, 2021
For further information, please call: (512) 305-8010

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TITLE 25. HEALTH SERVICES

PART 1. DEPARTMENT OF STATE HEALTH SERVICES

CHAPTER 228. RETAIL FOOD

The Executive Commissioner of the Texas Health and Human Services Commission (HHSC), on behalf of the Department of State Health Services (DSHS), proposes the repeal of §§228.1, 228.2, 228.31 - 228.45, 228.61 - 228.83, 228.101 - 228.125, 228.141 - 228.154, 228.171 - 228.186, 228.201 - 228.213, 228.221 - 228.225, 228.241 - 228.257, and 228.271 - 228.278, and new §§228.1, 228.2, 228.31, 228.32, 228.61 - 228.64, 228.141 - 228.143, 228.171, 228.172, 228.211, 228.221 - 228.225, and 228.241 - 228.246, concerning Retail Food Establishments.

BACKGROUND AND PURPOSE

The purpose of the proposed rules is to update the requirements for retail food establishments. Texas Health and Safety Code, Chapter 437, Regulation of Food Service Establishments, Retail Food Stores, Mobile Food Units, and Roadside Food Vendors, §437.0056 authorizes the Executive Commissioner of HHSC to adopt rules and minimum standards for food safety and the regulation of food service establishments, retail food stores, mobile food units, and roadside food vendors.

The proposed rules address the requirements in Senate Bill (S.B.) 476, 86th Legislature, Regular Session, 2019, which amended Texas Health and Safety Code, Chapter 437, by adding §437.025, Requirements for Dogs in Outdoor Dining Areas; Municipal Preemption.

S.B. 476 allows, but does not require, a food service establishment to permit a customer to be accompanied by a dog in an outdoor dining area. S.B. 476 also establishes requirements for the food establishment to allow pet dogs in outdoor dining areas, such as the establishment posting a sign in a conspicuous location stating that dogs are permitted; the customer and dog access from the exterior of the establishment; and the dog not entering the interior of the establishment. S.B. 476 requires the customer to keep the dog on a leash and control the dog. It also requires that the dog not be allowed on a seat, table, countertop, or similar surface. S.B 476 requires that in the area, the establishment does not prepare food or permit open food other than food that is being served to a customer.

The proposed rules include adoption by reference of the current U.S. Food and Drug Administration (FDA) 2017 Food Code. The proposed rules include requiring the person in charge to be a Certified Food Protection Manager (CFM), and the emergency operational plans for continued operation. The proposed rules update cooking time/temperature parameters for intact and non-intact meat and poultry. Further, the proposed rules add employee health signage, and edit and correct rule language identified by DSHS staff and stakeholders.

SECTION-BY-SECTION SUMMARY

The proposed repeal of Chapter 228, Subchapters A-J, removes the rules from Chapter 228, concerning Retail Food, and replaces Chapter 228 with new rules with a new title of Retail Food Establishments.

Proposed new Subchapter A creates rules related to General Provisions by implementing §228.1 Purpose and Regulations and §228.2 Definitions. Section 228.1 defines the purpose of the chapter and adopts by reference the Food Code. Texas law and rules in this chapter prevail over the adopted Food Code in event of conflict. Section 228.2 updates and revises definitions applicable to the chapter.

Proposed new Subchapter B creates rules related to Management and Personnel by implementing §228.31 Certified Food Protection Manager and Food Handler Requirements and §228.32 Reporting Symptoms and Diagnosis Signage. Section 228.31 addresses requirements for the employment of at least one certified food protection manager in the establishment and changes the time frame for successful completion of a food handler course from within 60 to within 30 days of employment. Section 228.32 requires that a sign, notifying employees of a need to report symptoms of foodborne illness to management, be placed next to each handwash sink.

Proposed new Subchapter C creates rules related to Food by implementing §228.61 Approved Sources for Exotic Game Animals; §228.62 Specifications for Receiving; §228.63 Buffet Notification; and §228.64 Donation of Foods. Section 228.61 lays out source, processing, and cooking requirements for the meat of exotic game animals to be served in food establishments. Section 228.62 sets forth receiving requirements for Grade A pasteurized milk, molluscan shellfish, chicken eggs, frozen milk products, and shell stock. Section 228.63 requires notification that clean tableware be used for each trip through a self-service area. Section 228.64 allows certain foods to be donated by food establishments and outlines safe-handling requirements for donated foods.

Proposed new Subchapter E creates rules related to Water, Plumbing, and Waste by implementing §228.141 Source; §228.142 Water Quality Standards; and §228.143 Water Distribution, Delivery, and Retention Systems. Section 228.141 requires that, in the absence of a community water system, a food establishment use a food establishment drinking water from a transient noncommunity water system that complies with the Texas Commission for Environmental Quality source requirements. Section 228.142 outlines standards and sampling requirements for public and nonpublic water systems utilized by food establishments. Section 228.143 sets standards for nonpublic water fixtures used to provide drinking water to food establishments.

Proposed new Subchapter F creates rules related to Physical Facilities by implementing §228.171 Wall and Ceiling Coverings and Coatings and §228.172 Dogs in Outdoor Dining Areas of a Food Establishment. Section 228.171 suggests that food establishment walls be light in color but allows for darker colors with sufficient lighting for proper cleaning. Section 228.172, in compliance with S.B. 476, provides requirements for establishment owners who wish to allow pet dogs in outdoor dining areas.

Proposed new Subchapter G creates a rule related to Poisonous or Toxic Materials by implementing §228.211 First Aid Supplies, Availability. Section 228.211 requires that each food establishment have available a first aid kit.

Proposed new Subchapter H creates rules related to Requirements Applicable to Certain Establishments by implementing §228.221 Mobile Food Units; §228.222 Temporary Food Establishments; §228.223 Bed and Breakfast; §228.224 Outfitter Operations; and §228.225 Self-Service Food Market. Section 228.221 outlines requirements for mobile food units, to include equipment, mobility, water and wastewater, and central preparation facility requirements. Section 228.222 outlines requirements for temporary food establishments, including water and wastewater, food temperatures, equipment and warewashing, and food handler certification for at least one person. Section 228.223 lists requirements for bed and breakfast extended, bed and breakfast food establishments, and bed and breakfast limited operations. Section 228.224 sets forth requirements for outfitter operations, to include requirements for a central preparation facility and a certified food protection manager. Section 228.225 contains requirements for self-service food markets, including automatic shut-off capabilities for refrigerated units holding time and temperature control for safety food (TCS food).

Proposed new Subchapter I create rules related to Compliance by implementing §228.241 Facility and Operating Plans; §228.242 Confidentiality, Trade Secrets; §228.243 Construction Inspection and Approval, Preoperational Inspections; §228.244 Performance and Risk-Based Inspection; §228.245 Competency of Inspectors and Access; and §228.246 Investigation and

Control. Section 228.241 contains conditions for plan review for those jurisdictions that require it. Section 228.242 requires the regulatory authority to treat as confidential trade secrets encountered in permitted food establishments. Section 228.243 allows for the possibility of preoperational inspections in those jurisdictions that require them. Section 228.244 requires the regulatory authority to conduct inspections of food establishments based on performance in past inspections and risks and hazards associated with foods served and processes used. Section 228.245 sets forth competency requirements for inspectors, allowing the option either to be a Registered Sanitarian in Texas or to demonstrate competency through knowledge and training. It also sets a time frame for correction of deficiencies cited during the inspection of temporary food establishments. Section 228.246 sets conditions for the release of employees from restriction or exclusion following recovery from illness.

FISCAL NOTE

Donna Sheppard, Chief Financial Officer, has determined that for each year of the first five years that the rules will be in effect, enforcing or administering the rules do not have foreseeable implications relating to costs or revenues of state government.

Ms. Sheppard has also determined that for each year of the first five years that the rules will be in effect, enforcing or administering the rules may have foreseeable implications relating to costs or revenues of local and county governments and public health districts. The costs may arise due to updates to local rules for newly referenced citations to the Food Code, update of software for digital inspection programs, and printing of new rules and inspection forms.

GOVERNMENT GROWTH IMPACT STATEMENT

DSHS has determined that during the first five years that the rules will be in effect:

(1) the proposed rules will not create or eliminate a government program;

(2) implementation of the proposed rules will not affect the number of DSHS employee positions;

(3) implementation of the proposed rules will result in no assumed change in future legislative appropriations;

(4) the proposed rules will not affect fees paid to DSHS;

(5) the proposed rules will create new rules;

(6) the proposed rules will repeal existing rules; and

(7) the proposed rules may change the number of individuals subject to the rules due to the requirement for more CFMs.

DSHS has insufficient information to determine the effect of the proposed rules.

SMALL BUSINESS, MICRO-BUSINESS, AND RURAL COMMUNITY IMPACT ANALYSIS

Donna Sheppard has also determined that there will be an adverse economic effect on small and micro-businesses. Food Code Subpart 2-102.12 requires that the person in charge always be on duty in a food establishment and be a CFM. This is a change from the current §228.33(a), which only requires the establishment to employ a single CFM. The change will require retail food establishments with extended hours potentially to employ more than one CFM in order to cover all hours of operation. While some larger jurisdictions with local health departments have already made this change (pursuant to Texas Health and Safety Code, §437.0075), this will be a change for food establishments under DSHS jurisdiction. DSHS regulates food establishments in towns and counties without local health departments, typically in rural areas.

DSHS estimates that the number of small and micro-businesses under DSHS jurisdiction subject to the change in the rules for a CFM is 7,870, although not every establishment included in that number would require more than one CFM. DSHS estimates that 60% of 7,870 small and micro-businesses might require more than one CFM to cover all hours of operation. The cost for CFM training and testing, which can be taken online with multiple options ranges from $80.00 - $152.00. The projected economic impact for a small and micro-business (food establishment) under DSHS jurisdiction is $80 - 152.00, with an average cost of $106.12, for each extra CFM required to cover all hours of operation.

DSHS determined that alternative methods to achieve the purpose of the proposed rules for small and micro-businesses would not be consistent with ensuring the health and safety of diners consuming food prepared in establishments regulated by DSHS.

LOCAL EMPLOYMENT IMPACT

The proposed rules will not affect a local economy.

COSTS TO REGULATED PERSONS

Texas Government Code, §2001.0045 does not apply to these rules because the rules are necessary to protect the health, safety, and welfare of the residents of Texas and the rules are necessary to implement legislation that does not specifically state that §2001.0045 applies to the rules.

PUBLIC BENEFIT AND COSTS

Stephen Pahl, Associate Commissioner, Consumer Protection Division, has determined that for each year of the first five years the rules are in effect, the public benefit will be enhanced food safety due to having a CFM on duty during all hours of operation and enhanced business opportunities due to the allowance of pet dogs in outdoor dining areas.

Donna Sheppard has also determined that for the first five years the rules are in effect, persons who are required to comply with the proposed rules may incur economic costs because of the change in the CFM requirement noted in the "SMALL BUSINESS, MICRO-BUSINESS, AND RURAL COMMUNITY IMPACT ANALYSIS" in this preamble. Some regulated businesses may now be required to train more than one CFM in order to cover all hours of operation.

REGULATORY ANALYSIS

DSHS has determined that this proposal is not a "major environmental rule" as defined by Government Code §2001.0225. "Major environmental rule" is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or the public health and safety of a state or a sector of the state. This proposal is not specifically intended to protect the environment or reduce risks to human health from environmental exposure.

TAKINGS IMPACT ASSESSMENT

DSHS has determined that the proposal does not restrict or limit an owner's right to his or her property that would otherwise exist

in the absence of government action and, therefore, does not constitute a taking under Texas Government Code §2007.043.

PUBLIC COMMENT

Questions about the content of this proposal may be directed to Joe Williams or Jason Guzman, DSHS Public Sanitation and Retail Food Safety Unit, at (512) 834-6753.

Written comments on the proposal may be submitted to Joe Williams or Jason Guzman, DSHS Public Sanitation and Retail Food Safety Unit, P.O. Box 149347, Austin, Texas 78714-9347 or by email to foodsestablishments@dshs.texas.gov.

To be considered, comments must be submitted no later than 31 days after the date of this issue of the *Texas Register.* Comments must be: (1) postmarked or shipped before the last day of the comment period; (2) hand-delivered at 8407 Wall Street, Austin, Texas 78754 before 5:00 p.m. on the last working day of the comment period; or (3) emailed before midnight on the last day of the comment period. If the last day to submit comments falls on a holiday, comments must be postmarked, shipped, or emailed before midnight on the following business day to be accepted. When emailing comments, please indicate "Comments on Proposed Rule 20R023" in the subject line.

SUBCHAPTER A. GENERAL PROVISIONS

25 TAC §228.1, §228.2

STATUTORY AUTHORITY

The proposed repeals are authorized by Texas Government Code, §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the efficient enforcement of Texas Health and Safety Code, Chapter 437; and Texas Health and Safety Code, §1001.075, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of health and human services by DSHS and for the administration of Texas Health and Safety Code, Chapter 1001.

The repeals implement Texas Government Code, Chapter 531 and Texas Health and Safety Code, Chapters 437 and 1001.

§228.1. Purpose.

§228.2. Definitions.

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

Filed with the Office of the Secretary of State on March 19, 2021.

TRD-202101134
Barbara L. Klein
General Counsel
Department of State Health Services
Earliest possible date of adoption: May 2, 2021
For further information, please call: (512) 834-6753

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25 TAC §228.1, §228.2

STATUTORY AUTHORITY

The proposed new rules are authorized by Texas Government Code, §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the efficient enforcement of Texas Health and Safety Code, Chapter 437; and Texas Health and Safety Code, §1001.075, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of health and human services by DSHS and for the administration of Texas Health and Safety Code, Chapter 1001.

The new rules implement Texas Government Code, Chapter 531 and Texas Health and Safety Code, Chapters 437 and 1001.

§228.1. Purpose and Regulations.

(a) The purpose of this chapter is to implement Texas Health and Safety Code, Chapter 437, Regulation of Food Service Establishments, Retail Food Stores, Mobile Food Units, and Roadside Food Vendors.

(b) The department adopts by reference the U.S. Food and Drug Administration (FDA) Food Code 2017 (Food Code) and the Supplement to the 2017 Food Code.

(c) The department does not adopt by reference the following sections, paragraphs, and subparagraph of the FDA Food Code, 3-202.13, 3-202.14(C), 3-202.18(A), 5-102.11, 5-102.13, 5-102.14, 5-104.11(B)(1), 6-101.11(B), 6-202.18, 8-201.11, 8-202.10, 8-203.10, 8-302.11-14, 8-303.10-30, 8-304.10, 8-304.20, 8-401.10, 8-401.20, 8-402.10, 8-402.20-40, 8-403.40, and 8-501.10-40, and the definitions for "accredited program," "drinking water," "food establishment," "game animal," "general use pesticide," "public water system," "regulatory authority," "safe material," "service animal," and "vending machine location."

(d) In the event of a conflict, Texas law and rules in this chapter prevail over the adopted Food Code.

§228.2. Definitions.

The following words and terms, when used in this chapter, shall have the following meanings unless the context clearly indicates otherwise.

(1) Accredited program--Food manager certification program that has been evaluated and listed by the department and conforms to standards set by the department in §229.172 of this title (relating to Accreditation of Certified Food Management Programs).

(2) Adulterated food--A food deemed to be adulterated as specified in the Texas Health and Safety Code, §431.081.

(3) Bed and breakfast extended--An establishment with more than seven rooms for rent or an establishment that provides food service other than breakfast to overnight guests.

(4) Bed and breakfast food establishment--A bed and breakfast that provides food service to customers in addition to its overnight guests.

(5) Bed and breakfast limited--An establishment that has seven or fewer rooms for rent, serves breakfast to overnight guests, and is not a retail food establishment.

(6) Central preparation facility--An approved and permitted facility or space where food is prepared, stored, and packaged.

(7) Code of Federal Regulations (CFR)--Citations to the CFR refer sequentially to the Title, Part, and Section numbers, such as 40 CFR 180.194 refers to Title 40, Part 180, Section 194.

(8) Common carrier--An individual or business that advertises to the public that it is available for hire to transport people or property, including food, in exchange for a fee.

(9) Cottage food production operation--An individual, operating out of the individual's home, who:

(A) produces at the individual's home:

(i) a baked good that is not a time and temperature control for safety food (TCS food), as defined in §229.661(b)(13) of this title (relating to Cottage Food Production Operations);

(ii) candy;

(iii) coated and uncoated nuts;

(iv) unroasted nut butters;

(v) fruit butters;

(vi) a canned jam or jelly;

(vii) a fruit pie;

(viii) dehydrated fruit or vegetables, including dried beans;

(ix) popcorn and popcorn snacks;

(x) cereal, including granola;

(xi) dry mix;

(xii) vinegar;

(xiii) pickled fruit or vegetables, including beets and carrots, that are preserved in vinegar, brine, or a similar solution at an equilibrium pH value of 4.6 or less;

(xiv) mustard;

(xv) roasted coffee or dry tea;

(xvi) a dried herb or dried-herb mix;

(xvii) plant-based acidified canned goods;

(xviii) fermented vegetable products, including products that are refrigerated to preserve quality;

(xix) frozen raw and uncut fruit or vegetables; or

(xx) any other food that is not a TCS food, as defined in §229.661(b)(13) of this title.

(B) has an annual gross income of $50,000 or less from the sale of food described by subparagraph (A) of this paragraph;

(C) sells foods produced under subparagraph (A) of this paragraph only directly to consumers; and

(D) delivers products to the consumer at the point of sale or another location designated by the consumer.

(10) Department--The Texas Department of State Health Services.

(11) Drinking water--Traditionally known as "potable water" and that meets the standards set forth in 30 TAC Chapter 290, Subchapter F (relating to Drinking Water Standards Governing Drinking Water Quality and Reporting Requirements for Public Water Systems). Drinking water includes the term "water" except where the term used connotes that the water is not potable, such as "boiler water," "mop water," "rainwater," "wastewater," and "non-drinking water."

(12) Event--A unique public gathering at which food products are served and for which an appropriate regulatory authority grants permission, whether by permit, license, or another official written document.

(13) Exotic animal--Member of a species of game animals not indigenous to this state, including axis deer, nilgai antelope, red sheep, or other cloven-hoofed ruminant animals.

(14) Food establishment--

(A) A food establishment is an operation that:

(i) stores, prepares, packages, serves, or vends food directly to the consumer, or otherwise provides food for human consumption, such as a restaurant, retail food store, satellite or catered feeding location, catering operation if the operation provides food directly to a consumer or to a conveyance used to transport people, market, vending machine location, self-service food market, conveyance used to transport people, institution, or food bank; and

(ii) relinquishes possession of food to a consumer directly, or indirectly through a delivery service, such as home delivery of grocery orders or restaurant takeout orders, or delivery service that is provided by common carriers.

(B) Food establishment includes:

(i) an element of the operation, such as a transportation vehicle or a central preparation facility that supplies a vending location or satellite feeding location unless the vending or feeding location is permitted by the regulatory authority; and

(ii) an operation that is conducted in a mobile, stationary, temporary, or permanent facility or location and where consumption is on or off the premises regardless if there is a charge for the food.

(C) Food establishment does not include:

(i) an establishment that offers only prepackaged foods that are not TCS foods;

(ii) a produce stand that only offers whole, uncut fresh fruits and vegetables;

(iii) a food processing plant, including one that is located on the premises of a food establishment;

(iv) a cottage food production operation;

(v) a bed and breakfast limited as defined in this section; or

(vi) a private home that receives catered or home-delivered food.

(15) Game animals--Wild animals that are indigenous to this state and not amenable to the Texas Meat and Poultry Inspection Act, Texas Health and Safety Code, Chapter 433, for which the hunter must obtain a hunting license from the Texas Parks and Wildlife Department before hunting animals, such as white-tailed deer, mule deer, pronghorn antelope, and big horn sheep.

(16) General use pesticide--A pesticide that is not classified by the United States Environmental Protection Agency for restricted use as specified in 40 CFR §152.175 or is not limited to use by or under the direct supervision of a certified applicator licensed by the Texas Department of Agriculture or by the Texas Structural Pest Control Service as applicable.

(17) Group residence--A private or public housing corporation or institutional facility that provides living quarters and meals. The term includes a domicile for unrelated persons, such as a retirement home, correctional facility, or a long-term care facility.

(18) Livestock--Cattle, sheep, swine, goats, horses, mules, other equine, poultry, domesticated rabbits, exotic animals, or domesticated game birds.

(19) Mobile food unit (MFU)--A vehicle-mounted, self or otherwise propelled, self-contained food service operation designed to be readily movable (including catering trucks, trailers, push carts, and roadside vendors) and used to store, prepare, display, serve or sell food. An MFU must completely retain its mobility at all times. An MFU does not include a stand or a booth. A roadside food vendor is classified as an MFU.

(20) Outfitter operation--Any operation, such as trail rides, bus tours, harbor cruises, or river raft trips, in which food is offered to patrons and which operates out of a central preparation location or food establishment.

(21) Plumbing Code--The International Plumbing Code, as amended, including appendices C, E, F, and G, published by the International Code Council as amended by 16 TAC §70.101 (relating to Amendments to Mandatory Building Code) or a Plumbing Code adopted by a local regulatory authority, whichever is more stringent.

(22) Private water system--A drinking water system that is not connected to a public water system and not regulated by the Texas Commission on Environmental Quality.

(23) Public water system--A drinking water system that complies with 30 TAC §§290.101 - 290.122 (relating to Drinking Water Standards Governing Drinking Water Quality and Reporting Requirements for Public Water Systems).

(24) Pushcart--A non-self-propelled MFU limited to serving foods requiring a limited amount of preparation as authorized by the regulatory authority and readily movable by one or two persons. A pushcart is classified as an MFU. A pushcart does not include non-self-propelled units owned and operated within a retail food store. This type of MFU requires the support of a central preparation facility.

(25) Regulatory authority--The department, the local (municipality, county, or public health district), federal enforcement body, or authorized representative having jurisdiction over the food establishment.

(26) Roadside food vendor--A person who operates a mobile retail food store from a temporary location adjacent to a public road or highway. Food is not prepared or processed by a roadside food vendor. A roadside food vendor is classified as an MFU.

(27) Safe material--An article manufactured from or composed of materials that may not reasonably be expected to result either directly or indirectly in the article becoming a component of or otherwise affecting the characteristics of any food. An additive that is used as specified in the Texas Health and Safety Code, Chapter 431, or other materials that are not additives and that are used in conformity with applicable regulations of the U.S. Food and Drug Administration.

(28) Self-service food market--A market that is unstaffed and offers prepackaged non-TCS food and prepackaged refrigerated or frozen TCS food that is stored in equipment that complies with §228.225 of this chapter (relating to Self-Service Food Market).

(29) Service animal--A canine that is individually trained to do work or perform tasks for the benefit of an individual with a disability, including a physical, sensory, psychiatric, intellectual or other mental disability as specified in Texas Health and Safety Code, §437.023.

(30) Vending machine location--The room, enclosure, space, or area where one or more vending machines are installed and operated and that includes the storage areas and areas on the premises that are used to service and maintain the vending machines. This does not include self-service food markets.

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General Counsel
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SUBCHAPTER B. MANAGEMENT AND PERSONNEL

25 TAC §§228.31 - 228.45

STATUTORY AUTHORITY

The repeals are authorized by Texas Government Code, §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the efficient enforcement of Texas Health and Safety Code, Chapter 437; and Texas Health and Safety Code, §1001.075, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of health and human services by DSHS and for the administration of Texas Health and Safety Code, Chapter 1001.

The repeals implement Texas Government Code, Chapter 531 and Texas Health and Safety Code, Chapters 437 and 1001.

§228.31. Responsibility.
§228.32. Knowledge.
§228.33. Certified Food Protection Manager and Food Handler Requirements.
§228.34. Duties.
§228.35. Responsibilities and Reporting Symptoms and Diagnosis.
§228.36. Conditions of Exclusions and Restrictions.
§228.37. Managing Exclusions and Restrictions.
§228.38. Hands and Arms.
§228.39. Fingernail Maintenance.
§228.40. Jewelry Prohibition.
§228.41. Outer Clothing, Clean Condition.
§228.42. Food Contamination Prevention.
§228.43. Hair Restraints.
§228.44. Animals, Handling Prohibitions.
§228.45. Contamination Events.

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25 TAC §228.31, §228.32

STATUTORY AUTHORITY

The new rules are authorized by Texas Government Code, §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the efficient enforcement of Texas Health and Safety Code, Chapter 437; and Texas Health and Safety Code, §1001.075, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and

provision of health and human services by DSHS and for the administration of Texas Health and Safety Code, Chapter 1001.

The new rules implement Texas Government Code, Chapter 531 and Texas Health and Safety Code, Chapters 437 and 1001.

§228.31. Certified Food Protection Manager and Food Handler Requirements.

(a) The original food manager certificate shall be posted in the food establishment in a location that is conspicuous to consumers.

(b) Except in a temporary food establishment, at least one certified food protection manager must be employed by each food establishment.

(c) All food employees, except for the certified food protection manager, shall successfully complete an accredited food handler training course, within 30 days of employment. This requirement does not apply to temporary food establishments.

(d) The food establishment shall maintain on premises a certificate of completion of the food handler training course for each food employee.

§228.32. Reporting Symptoms and Diagnosis Signage.

A food establishment shall post a sign or poster, clearly visible to food employees, by all handwashing sinks. The sign or poster shall notify food employees to report symptoms and diagnosis information about their health as it relates to diseases that are transmissible through food.

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SUBCHAPTER C. FOOD

25 TAC §§228.61 - 228.83

STATUTORY AUTHORITY

The repeals are authorized by Texas Government Code, §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the efficient enforcement of Texas Health and Safety Code, Chapter 437; and Texas Health and Safety Code, §1001.075, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of health and human services by DSHS and for the administration of Texas Health and Safety Code, Chapter 1001.

The repeals implement Texas Government Code, Chapter 531 and Texas Health and Safety Code, Chapters 437 and 1001.

§228.61. Condition Safe, Unadulterated, and Honestly Presented.
§228.62. Approved Sources.
§228.63. Specifications for Receiving.
§228.64. Molluscan Shellfish, Original Container and Records.
§228.65. Preventing Contamination by Employees.
§228.66. Preventing Food and Ingredient Contamination.
§228.67. Preventing Contamination From Ice Used as a Coolant.
§228.68. Preventing Contamination From Equipment, Utensils, and Linens.
§228.69. Preventing Contamination From the Premises.
§228.70. Preventing Contamination by Consumers.
§228.71. Cooking.
§228.72. Freezing.
§228.73. Reheating for Hot Holding.
§228.74. Juice Packaged in a Food Establishment.
§228.75. Temperature and Time Control.
§228.76. Specialized Processing Methods, Variance Requirement.
§228.77. Clostridium Botulinum and Listeria Monocytogenes Controls.
§228.78. Food Identity, Presentation, On-premises Labeling, and Accurate Representation.
§228.79. Labeling.
§228.80. Consumer Advisory.
§228.81. Contaminated Food, Disposition.
§228.82. Additional Safeguards, Special Requirements for Serving Highly Susceptible Populations.
§228.83. Donation of Foods.

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25 TAC §§228.61 - 228.64

STATUTORY AUTHORITY

The new rules are authorized by Texas Government Code, §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the efficient enforcement of Texas Health and Safety Code, Chapter 437; and Texas Health and Safety Code, §1001.075, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of health and human services by DSHS and for the administration of Texas Health and Safety Code, Chapter 1001.

The new rules implement Texas Government Code, Chapter 531 and Texas Health and Safety Code, Chapters 437 and 1001.

§228.61. Approved Sources for Exotic Game Animals.

(a) Exotic animals. If exotic animals are received for sale or service, they shall:

(1) be commercially raised for food; and

(A) raised, slaughtered, processed, and deemed to be "inspected and approved" under an inspection program administered by United States Department of Agriculture (USDA) in accordance with 9 CFR 352, Exotic Animals; Voluntary Inspection; or

(B) raised, slaughtered, processed, and deemed to be "inspected and passed" under a meat and poultry inspection program administered by the department or any other state meat inspection program deemed equal to USDA inspection;

(2) as allowed by law, for exotic animals that are live caught, be slaughtered and processed as required in paragraph (1)(A) or (B) of this subsection; and

(3) as allowed by law, for exotic animals that are field dressed:

(A) receive an antemortem and postmortem examination by the appropriate inspection personnel as described in paragraph (1)(A) or (B) of this subsection; and

(B) be transported and processed according to the requirements specified by the appropriate regulatory authority as described in paragraph (1)(A) or (B) of this subsection.

(b) Cooking. Exotic animals shall be cooked to heat all parts of the food to a temperature and for a time that complies with one of the methods for cooking game animals according to Food Code, §3-401.11, and under a voluntary inspection program as specified in subsection (a) of this section.

§228.62. Specifications for Receiving.

(a) Temperature.

(1) Grade A pasteurized milk shall be received in refrigerated equipment that maintains an ambient air temperature of seven degrees Celsius (45 degrees Fahrenheit) or less.

(2) Molluscan shellfish shall be received in refrigerated equipment or on ice that maintains a temperature of seven degrees Celsius (45 degrees Fahrenheit) or less, as required in the Texas Molluscan Shellfish Rules, §241.61(a) of this title (relating to Molluscan Shell Stock Temperature Control).

(b) Chicken Eggs. Chicken eggs shall be received clean and sound and may not exceed the restricted egg tolerances for U.S. Consumer Grade B as specified in 7 CFR 56, Voluntary Grading of Shell Eggs and United States Standards, Grades, and Weight Classes for Shell Eggs, and 9 CFR 590, Inspection of Eggs and Egg Products.

(c) Frozen milk products. Frozen milk products, such as ice cream, shall be obtained pasteurized in accordance with the Frozen Desserts Manufacturer Licensing Act, Texas Health and Safety Code, Chapter 440, and 21 CFR 135, Frozen Desserts.

(d) Shell stock identification. Shell stock shall be obtained in containers bearing legible source identification tags or labels that are affixed by the harvester or dealer that depurates, ships, or reships the shell stock, as specified in §§241.50 - 241.71 of this title (relating to Molluscan Shellfish).

§228.63. Buffet Notification.

A card, sign, or other effective means of notification shall be displayed to notify consumers that clean tableware is to be used upon return to self-service areas, such as salad bars and buffets as specified in Food Code, §3-304.16.

§228.64. Donation of Foods.

(a) Previous service. Except as specified in paragraphs (1) and (2) of this subsection, foods which have been previously served to a consumer may not be donated.

(1) Packaged time and temperature control for safety foods (TCS foods), such as unopened milk, may be re-served or donated if immediately stored in a cooling bin maintained at five degrees Celsius (41 degrees Fahrenheit) or below.

(2) The following food products may be re-served or donated.

(A) Packaged non-TCS foods.

(B) Whole fruit, such as apples or bananas.

(b) Unpackaged and unserved foods. Unpackaged and unserved TCS foods may be donated if:

(1) the temperature of the food is at or below five degrees Celsius (41 degrees Fahrenheit), or an ambient temperature of seven degrees Celsius (45 degrees Fahrenheit) for raw shell eggs, at the time of donation, and is protected from contamination;

(2) the food has been at or above 57 degrees Celsius (135 degrees Fahrenheit) during hot holding and service, and subsequently refrigerated to meet the time and temperature requirements in Food Code, §3-501.14 and §3-501.15, or maintained at proper holding temperatures required in Food Code, §3-501.16;

(3) the donor can substantiate that the food recipient has the facilities to meet the transportation, storage, and reheating requirements of this chapter; and

(4) the food is to be transported by the food recipient directly to a consumer, the recipient only needs to meet the transportation requirements in this chapter, including holding temperatures.

(c) Labeling. Donated foods transported offsite shall be labeled with the name of the food, the source of the food, and the date of preparation.

(d) Shelf life. Donated TCS foods may not exceed the shelf life for leftover foods outlined in this chapter.

(e) Damaged foods. Heavily rim or seam-dented canned foods, or packaged foods without the manufacturer's complete labeling shall not be donated.

(f) Distressed foods.

(1) Foods which are considered distressed, such as foods which have been subjected to fire, flooding, excessive heat, smoke, radiation, other environmental contamination, or prolonged storage shall not be directly donated for consumption by the consumer.

(2) Such foods in paragraph (1) of this subsection may be sold or donated to a licensed food salvage establishment if permitted under the provisions of the Texas Health and Safety Code, Chapter 432.

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SUBCHAPTER D. EQUIPMENT, UTENSILS, AND LINENS

25 TAC §§228.101 - 228.125

STATUTORY AUTHORITY

The repeals are authorized by Texas Government Code, §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the efficient enforcement of Texas Health and Safety Code, Chapter 437; and Texas Health and

Safety Code, §1001.075, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of health and human services by DSHS and for the administration of Texas Health and Safety Code, Chapter 1001.

The repeals implement Texas Government Code, Chapter 531 and Texas Health and Safety Code, Chapters 437 and 1001.

§228.101. Multiuse Materials.

§228.102. Single-service and Single-use, Characteristics.

§228.103. Durability and Strength.

§228.104. Cleanability.

§228.105. Accuracy of Temperature Measuring Devices.

§228.106. Functionality of Equipment.

§228.107. Equipment, Numbers and Capacities.

§228.108. Utensils, Temperature Measuring Devices, and Testing Devices.

§228.109. Location and Installation, Equipment, Clothes Washers and Dryers, and Storage Cabinets, Contamination Prevention.

§228.110. Installation.

§228.111. Equipment, Maintenance and Operation.

§228.112. Utensils and Temperature and Pressure Measuring Devices.

§228.113. Cleaning of Equipment and Utensils.

§228.114. Frequency of Cleaning.

§228.115. Methods of Cleaning.

§228.116. Sanitization Objectives, Food-contact Surfaces and Utensils.

§228.117. Sanitization Frequency, Before Use After Cleaning.

§228.118. Sanitization Methods, Hot Water and Chemicals.

§228.119. Laundering, Clean Linens.

§228.120. Laundering, Frequency, Specifications.

§228.121. Laundering Methods.

§228.122. Drying, Equipment and Utensils.

§228.123. Lubricating and Reassembling.

§228.124. Storage.

§228.125. Preventing Contamination.

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SUBCHAPTER E. WATER, PLUMBING, AND WASTE

25 TAC §§228.141 - 228.154

STATUTORY AUTHORITY

The repeals are authorized by Texas Government Code, §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the efficient enforcement of Texas Health and Safety Code, Chapter 437; and Texas Health and Safety Code, §1001.075, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of health and human services by DSHS and for the administration of Texas Health and Safety Code, Chapter 1001.

The repeals implement Texas Government Code, Chapter 531 and Texas Health and Safety Code, Chapters 437 and 1001.

§228.141. Source.

§228.142. Water Quality Standards.

§228.143. Water Quantity and Availability.

§228.144. Water Distribution, Delivery, and Retention Systems.

§228.145. Plumbing Systems, Approved Materials.

§228.146. Plumbing Design, Construction, and Installation.

§228.147. Plumbing, Numbers and Capacities.

§228.148. Plumbing, Location and Placement.

§228.149. Plumbing, Operation and Maintenance.

§228.150. Sewage Retention, Drainage, and Delivery.

§228.151. Disposal Facility.

§228.152. Refuse, Recyclables, and Returnables, Facilities on the Premises.

§228.153. Refuse Removal.

§228.154. Facilities for Disposal and Recycling, Community or Individual Facility.

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25 TAC §§228.141 - 228.143

STATUTORY AUTHORITY

The new rules are authorized by Texas Government Code, §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the efficient enforcement of Texas Health and Safety Code, Chapter 437; and Texas Health and Safety Code, §1001.075, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of health and human services by DSHS and for the administration of Texas Health and Safety Code, Chapter 1001.

The new rules implement Texas Government Code, Chapter 531 and Texas Health and Safety Code, Chapters 437 and 1001.

§228.141. Source.

A water source obtained from other than a community public water system shall be sampled and analyzed in accordance with the requirements found in 30 TAC Chapter 290, Subchapter F (relating to Drinking Water Standards Governing Drinking Water Quality and Reporting Requirements for Public Water Systems), concerning transient noncommunity water systems.

§228.142. Water Quality Standards.

(a) Public and private water systems.

(1) Water from a public water system shall meet 40 CFR 141 - National Primary Drinking Water Regulations, state drinking water quality standards in accordance with 30 TAC §§290.38 - 290.47 (relating to Rules and Regulations for Public Water Systems), and 30 TAC §§290.101 - 290.114, 290.117 - 290.119, 290.121, and 290.122 (relating to Drinking Water Standards Governing Drinking Water Quality and Reporting Requirements for Public Water Systems); and

(2) Water from a nonpublic water system shall meet the requirements of 30 TAC Chapter 290, Subchapter F (relating to Drinking Water Standards Governing Drinking Water Quality and Reporting Requirements for Public Water Systems), pertaining to transient noncommunity water systems.

(b) Sampling. Water from a nonpublic water system shall be sampled and tested according to 30 TAC Chapter 290, Subchapter F, concerning transient noncommunity water systems, except nondrinking water.

(c) Sample report. The most recent sample report for the nonpublic water system shall be retained on file in the food establishment, or the report shall be maintained as specified in 30 TAC Chapter 290, Subchapter F, concerning transient noncommunity water systems.

§228.143. Water Distribution, Delivery, and Retention Systems.

Nonpublic water mains, water pumps, pipes, hoses, connections, and other appurtenances shall meet the requirements of 30 TAC Chapter 290, Subchapter F (relating to Drinking Water Standards Governing Drinking Water Quality and Reporting Requirements for Public Water Systems), concerning transient noncommunity water systems.

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SUBCHAPTER F. PHYSICAL FACILITIES

25 TAC §§228.171 - 228.186

STATUTORY AUTHORITY

The repeals are authorized by Texas Government Code, §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the efficient enforcement of Texas Health and Safety Code, Chapter 437; and Texas Health and Safety Code, §1001.075, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of health and human services by DSHS and for the administration of Texas Health and Safety Code, Chapter 1001.

The repeals implement Texas Government Code, Chapter 531 and Texas Health and Safety Code, Chapters 437 and 1001.

§228.171. Indoor Areas, Surface Characteristics.
§228.172. Outdoor Areas, Surface Characteristics.
§228.173. Floors, Walls, and Ceilings.
§228.174. Functionality.
§228.175. Handwashing Sinks.
§228.176. Toilets and Urinals.
§228.177. Lighting Intensity.
§228.178. Ventilation, Mechanical.
§228.179. Dressing Areas and Lockers, Designation.
§228.180. Service Sinks, Availability.
§228.181. Handwashing Sinks, Conveniently Located.
§228.182. Toilet Rooms, Convenience and Accessibility.
§228.183. Employee Accommodations, Designated Areas.
§228.184. Distressed Merchandise, Segregation and Location.
§228.185. Receptacles, Waste Handling Units, and Designated Storage Areas.
§228.186. Premises, Buildings, Systems, Rooms, Fixtures, Equipment, Devices, and Materials.

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25 TAC §228.171, §228.172

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The new rules implement Texas Government Code, Chapter 531 and Texas Health and Safety Code, Chapters 437 and 1001.

§228.171. Wall and Ceiling Coverings and Coatings.

(a) Walls including non-supporting partitions, wall covering and ceilings of the walk-in refrigeration units, food preparation areas, equipment and utensil washing areas, toilet rooms and vestibules should be light in color or meet the requirements and approval of the regulatory authority.

(b) Darker-colored coverings for the items listed in subsection (a) of this section may require additional lighting, as specified in Food Code, §6-303.11, or meet the requirements set by the regulatory authority, to allow cleaning of the surface.

§228.172. Dogs in Outdoor Dining Areas of a Food Establishment.

Dogs may be allowed in outdoor dining areas of a food establishment if:

(1) the establishment posts a sign in a conspicuous location in the area stating that dogs are allowed;

(2) the customer and dog access the area directly from the exterior of the establishment;

(3) the dog does not enter the interior of the establishment;

(4) the customer keeps the dog on a leash and controls the dog;

(5) the customer does not allow the dog on a seat, table, countertop, or similar surface; and

(6) in the area, the establishment does not:

(A) prepare food; or

(B) permit open food other than food that is being served to a customer; and

(7) the requirements specified in this section do not apply to service animals or service animals in training.

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SUBCHAPTER G. POISONOUS OR TOXIC MATERIALS

25 TAC §§228.201 - 228.213

STATUTORY AUTHORITY

The repeals are authorized by Texas Government Code, §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the efficient enforcement of Texas Health and Safety Code, Chapter 437; and Texas Health and Safety Code, §1001.075, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of health and human services by DSHS and for the administration of Texas Health and Safety Code, Chapter 1001.

The repeals implement Texas Government Code, Chapter 531 and Texas Health and Safety Code, Chapters 437 and 1001.

§228.201. Original Containers, Identifying Information, Prominence.

§228.202. Working Containers, Common Name.

§228.203. Storage, Separation.

§228.204. Presence and Use.

§228.205. Container Prohibitions, Poisonous or Toxic Material Containers.

§228.206. Chemicals.

§228.207. Lubricants, Incidental Food Contact, Criteria.

§228.208. Pesticides.

§228.209. Medicines.

§228.210. First Aid Supplies, Availability.

§228.211. First Aid Supplies, Storage.

§228.212. Other Personal Care Items, Storage.

§228.213. Storage and Display, Separation.

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

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Barbara L. Klein
General Counsel
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25 TAC §228.211

STATUTORY AUTHORITY

The new rule is authorized by Texas Government Code, §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the efficient enforcement of Texas Health and Safety Code, Chapter 437; and Texas Health and Safety Code, §1001.075, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of health and human services by DSHS and for the administration of Texas Health and Safety Code, Chapter 1001.

The new rule implements Texas Government Code, Chapter 531 and Texas Health and Safety Code, Chapters 437 and 1001.

§228.211. First Aid Supplies, Availability.

A first aid kit shall be provided in all food establishments.

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

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SUBCHAPTER H. REQUIREMENTS APPLICABLE TO CERTAIN ESTABLISHMENTS

25 TAC §§228.221 - 228.225

STATUTORY AUTHORITY

The repeals are authorized by Texas Government Code, §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the efficient enforcement of Texas Health and Safety Code, Chapter 437; and Texas Health and Safety Code, §1001.075, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of health and human services by DSHS and for the administration of Texas Health and Safety Code, Chapter 1001.

The repeals implement Texas Government Code, Chapter 531 and Texas Health and Safety Code, Chapters 437 and 1001.

§228.221. Mobile Food Units.

§228.222. Temporary Food Establishments.

§228.223. Bed and Breakfast.

§228.224. Outfitter Operations.

§228.225. Self-Service Food Market.

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

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25 TAC §§228.221 - 228.225

STATUTORY AUTHORITY

The new rules are authorized by Texas Government Code, §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the efficient enforcement of Texas Health and Safety Code, Chapter 437; and Texas Health and Safety Code, §1001.075, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of health and human services by DSHS and for the administration of Texas Health and Safety Code, Chapter 1001.

The new rules implement Texas Government Code, Chapter 531 and Texas Health and Safety Code, Chapters 437 and 1001.

§228.221. Mobile Food Units.

(a) Mobile food unit provisions.

(1) General. Except as otherwise provided in this paragraph and in paragraph (2) of this subsection, the regulatory authority:

(A) may impose additional requirements to protect against health hazards related to the conduct of the food establishment as a mobile operation;

(B) may prohibit the sale of some or all time and temperature control for safety foods (TCS foods); and

(C) when no health hazard will result, may waive or modify requirements of this section relating to physical facilities, except those requirements as specified in paragraphs (7) - (9) of this subsection, subsection (c)(1)(A) - (E) of this section, and Food Code, Subparts 3-401, 3-402, 3-403, 3-404, and 3-501.

(2) Restricted operation. A mobile food unit (MFU) that serves only food that is prepared, packaged in individual servings, transported and stored under conditions meeting the requirements of this chapter, or beverages that are non-time and temperature control for safety food and are dispensed from covered urns or other protected equipment, need not comply with the requirements of this chapter, relating to the necessity of water and sewage systems nor to those requirements, relating to the cleaning and sanitization of equipment and utensils if the required equipment for cleaning and sanitization exists at its central preparation facility.

(3) Readily movable.

(A) The regulatory authority prohibits alteration, removal, attachments, additions, placement, or change in, under, or upon the MFU that prevents or otherwise reduces ready mobility.

(B) A regulatory authority may require an MFU to come, on an annual basis or as often as required, to a location designated by the regulatory authority as proof that the MFU is readily moveable.

(4) Initial Permitting Inspection. The regulatory authority requires an MFU to come to a location designated by the regulatory authority. The mobile unit must be totally operable at time of inspection, including handwash facilities, warewash facilities, refrigeration, and wastewater disposal. Required documentation to have available includes:

(A) Certified Food Protection Manager Certification.

(B) Central Preparation Facility Authorization (if required). A signed letter of authorization is required, to verify facility use, if the central preparation facility is not owned by the mobile unit operator.

(C) Central Preparation Facility Inspection Report. A copy of the most current health inspection of the central preparation facility must be maintained on the mobile unit at all times.

(D) Servicing Area Authorization. A signed letter of authorization may be required by the regulatory authority to verify service area use, if the servicing area is not owned by the mobile unit operator.

(E) Menu. A menu of all food items to be sold.

(5) Single-service articles. An MFU shall provide only single service articles for use by the consumer.

(6) Equipment, numbers, and capacities.

(A) Cooling, heating, and holding capacities. Equipment for cooling and heating food, and holding cold and hot food, shall be sufficient in number and capacity to provide food temperatures as specified under Food Code, Chapter 3 - Food.

(B) Manual warewashing, sink compartment requirements.

(i) A sink with at least three compartments shall be provided for manually washing, rinsing, and sanitizing equipment and utensils as specified in Food Code, Paragraph 4-301.12(A).

(ii) Sink compartments shall be large enough to accommodate immersion of the largest equipment and utensils as specified in Food Code, Paragraph 4-301.12(B).

(C) At least one handwashing sink shall be available for convenient use by employees and properly provisioned in accordance with Food Code, §6-301.11-12.

(7) Mobile water system materials, design, and operation. MFU water systems shall meet the requirements of Food Code, Part 5-3.

(8) MFU drinking water tank shall meet the requirements of Food Code, §5-303.13.

(A) Fill hose and water holding tank shall be labeled as "Potable Water."

(B) Drinking water in an MFU holding tank shall be tested for contamination by sampling upon request by the regulatory authority.

(9) Sewage and other liquid waste.

(A) If liquid waste results from operation of an MFU, the waste shall be stored in a permanently installed retention tank for waste retention.

(B) A leak-proof sewage holding tank in an MFU shall meet the requirements of Food Code, §5-401.11 for capacity and drainage.

(C) All connections on the vehicle for servicing the MFU waste disposal facilities shall be of a different size or type than those used for supplying potable water to the MFU.

(D) Discharge liquid waste shall not be discharged from the retention tank while the MFU is in motion.

(E) Flushing a waste retention tank shall meet the requirements of Food Code, §5-402.15.

(F) Removing MFU wastes shall meet the requirements of Food Code, §5-402.14.

(G) Liquid waste holding tank shall be labeled as "waste water."

(10) MFU water and wastewater exemption.

(A) A roadside vendor that sells only prepackaged food is exempt from the requirements of this chapter relating to water and wastewater.

(B) An MFU that prepares food requiring no water for operations and no hand contact with food is exempt from the requirements of this chapter relating to water and wastewater if the required cleaning and sanitization equipment exists at its central preparation facility. Chemically treated towelettes for handwashing may be used as specified in Food Code, Paragraph 5-203.11(C).

(11) Toilet rooms, convenience and accessibility. Toilet rooms shall be conveniently located and accessible to employees during all hours of operation.

(b) Central preparation facility.

(1) Supplies, cleaning, and servicing operations. An MFU shall operate from a central preparation facility or other fixed food establishment and shall report to such location daily for supplies, cleaning, and servicing operations.

(2) Construction. The central preparation facility or other fixed food establishment, used as a base of operation for an MFU, shall be constructed and operated in compliance with the requirements of Food Code, Chapter 6 - Physical Facilities.

(c) Outdoor servicing area and operations.

(1) Protection.

(A) An MFU servicing area shall include at least overhead protection for any supplying, cleaning, or servicing operation. Those areas used only for the loading of water or the discharge of sewage and other liquid waste, through the use of a closed system of hoses, need not be provided with overhead protection.

(B) Within the servicing area, the location provided for the flushing and drainage of liquid wastes shall be separate from the location provided for potable water servicing and for the loading and unloading of food and related supplies.

(C) A servicing area will not be required where only packaged food is placed on the MFU or where an MFU does not contain waste retention tanks.

(D) The surface of the servicing area shall be constructed of a smooth nonabsorbent material, such as concrete or machine-laid asphalt and shall be maintained in good repair, kept clean, and be graded to drain.

(E) Potable water servicing equipment shall be installed in the servicing area according to the Plumbing Code and shall be stored and handled in a way that protects the water and equipment from contamination.

(2) Construction exemption. The construction of the walls and ceilings of the servicing area is exempted from the provisions of Food Code, §6-201.11.

§228.222. Temporary Food Establishments.

(a) General. The regulatory authority may impose additional requirements to protect against health hazards related to the conduct of the temporary food establishment, may prohibit the sale of some or all time and temperature control for safety foods (TCS foods), and when no health hazard will result, such as children's neighborhood beverage stands, may waive or modify requirements of this chapter.

(1) Foods that are not prepared on-site or that require extensive preparation or cooking must be prepared at a licensed food establishment.

(2) Each temporary establishment may be required by the regulatory authority to have at least one person on-site who has a minimum of an accredited food handler certification.

(b) Food temperatures. All food temperature requirements shall be met as contained in Food Code, Subparts 3-202, 3-401-403, and 3-501, §228.62 of this chapter (relating to Specifications for Receiving), and §228.64 of this chapter (relating to Donation of Foods).

(c) Ice. Ice that is consumed or that contacts food shall have been made under conditions meeting the requirements of Food Code, Chapter 3 - Food. The ice shall be obtained only in blocked, chipped, crushed, or cubed form and in single-use safe plastic or wet-strength paper bags filled and sealed at the point of manufacture. Ice for consumption shall be held in the bags until it is dispensed and be dispensed in a way that protects it from contamination.

(d) Equipment and utensils.

(1) Design and construction. Equipment and utensils shall be designed and constructed to be durable and to retain their characteristic qualities under normal use conditions.

(2) Location and installation. Equipment shall be located and installed and cleaned in a way that prevents food contamination and that also facilitates cleaning of the temporary food establishment.

(3) Hot and cold holding equipment. Equipment for cooling or heating food and holding cold or hot food shall be adequate in number and capacity to provide food temperatures as specified in Food Code, Subparts 3-401-403 and 3-501.

(4) Protection from contamination. Food-contact surfaces of equipment shall be protected from contamination by consumers and other sources. Where necessary to prevent contamination, effective shields for such equipment shall be provided.

(5) Alternative manual warewashing. Alternative manual warewashing equipment, such as receptacles that substitute for the compartments of a three-compartment sink, may be used when there are special cleaning needs or constraints and the regulatory authority has approved the use of alternative equipment. Each compartment shall be large enough to immerse the largest piece of equipment that will be used. A means to heat water must also be provided.

(e) Single-service articles. A temporary food establishment shall provide only single-service articles for use by the consumer.

(f) Water.

(1) Water from an approved source shall be made available in a temporary food establishment for food preparation, handwashing, and for cleaning and sanitizing utensils and equipment.

(2) Water does not need to be under pressure but shall come from approved sources which include:

(A) commercially bottled drinking water;

(B) closed portable water containers;

(C) enclosed vehicular water tanks;

(D) on-premise water storage tanks; or

(E) piping, tubing or hoses connected to an approved source.

(g) Wet storage. Packaged food may not be stored in direct contact with ice or water if the food is subject to the entry of water because of the nature of its packaging, wrapping, or container or its positioning in the ice or water.

(h) Sewage. All waste water and sewage generated from the temporary food establishment shall be disposed of through an approved sanitary sewage system that is:

(1) a public sewage system; or

(2) an individual sewage disposal system that is sized, constructed, maintained, and operated according to 30 TAC Chapter 285 (relating to On-Site Sewage Facilities).

(i) Handwashing. Handwashing facilities shall include a container with a spigot that provides potable, clean, warm water; a wastewater container; soap; disposable towels; and a waste receptacle. Handwashing facilities are not required if the only food items offered are commercially pre-packaged foods that are dispensed in their original containers.

(j) Floors. If graded to drain, a floor may be concrete, machine-laid asphalt, dirt, or gravel covered with mats, ply-wood, removable platforms, duckboards if covered with mats, or other suitable materials approved by the regulatory authority, such as tarps, that effectively control dust and mud.

(k) Ceilings and outer openings of food preparation areas.

(1) Walls and Ceilings. Walls and ceilings shall be made of wood, canvas, or other materials that protect the interior of the establishment from the weather, windblown dust, birds, and debris.

(2) Outer openings. The outer openings shall be protected against entry of insects and rodents by:

(A) 16 mesh to 25.4 millimeters (16 mesh to 1 inch) screens;

(B) properly designed and installed air curtains; or

(C) other effective means.

(3) Exclusion provision. Paragraph (2) of this subsection does not apply if flying insects and other pests are absent due to the location of the temporary food establishment or other limiting conditions.

§228.223. Bed and Breakfast.

(a) General.

(1) A bed and breakfast extended, in addition to licensing with the applicable regulatory authority, shall comply with the minimum requirements of this section if the establishment:

(A) has more than seven rooms for rent; or

(B) provides food service other than breakfast to overnight guests.

(2) A bed and breakfast food establishment that provides food service to customers in addition to its overnight guests must comply with the rules and regulations applicable to retail food establishments, including licensing with the applicable regulatory authority.

(3) A bed and breakfast limited:

(A) has seven or fewer rooms for rent;

(B) serves only breakfast to overnight guests;

(C) is not a retail food establishment; and

(D) complies with subsection (b) of this section.

(b) Certified food protection manager. The owner or manager shall successfully complete a food manager's certification course accredited by this department.

(c) Food supplies. Food shall be obtained from approved sources in accordance with Food Code, Subpart 3-201, §228.61 of this chapter (relating to Approved Sources for Exotic Game Animals), and §228.62 of this chapter (relating to Specifications for Receiving) and shall be in sound condition and be safe for human consumption.

(d) Food preparation and protection.

(1) Food preparation and protection. Food shall be prepared and protected in accordance with Food Code, Chapter 3 - Food.

(2) Temperature requirements. All food temperature requirements shall be met as contained in Food Code, Subparts 3-202, 3-401-403, and 3-501, §228.62 of this chapter, and §228.64 of this chapter (relating to Donation of Foods).

(e) Cleaning and sanitizing.

(1) Manual. A three-compartment sink shall be used if washing, rinsing, and sanitizing of utensils and equipment is done manually; or a two-compartment sink may be utilized if single service tableware is provided, and if an approved detergent sanitizer is used.

(2) Mechanical. Cleaning and sanitizing may be done by spray-type or immersion dishwashing machines or by any other type of machine or device if it is demonstrated that it thoroughly cleans and sanitizes equipment and utensils either by chemical or mechanical sanitization.

(f) Personal hygiene. Employees shall conform to good hygienic practices as required in in Food Code, Subparts 2-301-304 and 2-401-402.

(g) Employee restrooms. A restroom shall be available for use by employees.

(h) Equipment and utensil design and construction. All equipment and utensils shall be constructed of safe materials and maintained in good repair.

(i) Handwash sinks.

(1) Location. An accessible and conveniently located handwash sink shall be provided in or immediately adjacent to food preparation areas and restrooms.

(2) Intended use. Handwash sinks shall be used for no other purpose other than handwashing.

(j) Food-contact surfaces. All food contact surfaces, counters, or work surfaces in the bed and breakfast establishment shall be smooth, non-absorbent and easily cleanable.

(k) Insect proof/rodent proof.

(1) Construction. Food service preparation and storage areas shall be constructed and maintained to prevent the entry of pests and other vermin.

(2) Chemical control. Pesticides and rodenticides shall be applied in accordance with Food Code, Subpart 7-206.

(l) Equipment. Equipment shall be provided to maintain time and temperature control for safety foods (TCS foods) at the temperatures required in accordance with Food Code, Chapter 3 - Food.

(m) Garbage receptacles. Impervious receptacles shall be provided for storage of garbage and refuse.

(n) Sewage. Sewage shall be disposed through an approved facility that is:

(1) a public sewage system; or

(2) an individual sewage disposal system that is sized, constructed, maintained, and operated according to law in 30 TAC Chapter 285 (relating to On-Site Sewage Facilities).

(o) Water supply. Hot and cold water under pressure shall be provided and shall be from an approved source that meets the standards in accordance with:

(1) state drinking water quality standards in accordance with 30 TAC §§290.38 - 290.47 (relating to Rules and Regulations for Public Water Systems), and 30 TAC §§290.101 - 290.114, 290.117 - 290.119, 290.121, and 290.122 (relating to Drinking Water Standards Governing Drinking Water Quality and Reporting Requirements for Public Water Systems); or

(2) private water system standards as provided in 30 TAC Chapter 290, Subchapter F (relating to Drinking Water Standards Governing Drinking Water Quality and Reporting Requirements for Public Water Systems), concerning transient noncommunity water systems.

§228.224. Outfitter Operations.

(a) General. Requirements in this section are specific for outfitter operations. The regulatory authority may impose additional requirements to protect against health hazards that may be specific to these operations.

(b) Food supplies. Food supplies, including ice, shall be obtained from approved sources described in Food Code, §3-201.11-17 (relating to Sources), §228.61 of this chapter (relating to Approved Sources for Exotic Game Animals), and §228.62 of this chapter (relating to Specifications for Receiving). No home-prepared products shall be offered.

(c) Food temperatures. All food temperature requirements shall be met as contained in Food Code, Subparts 3-202, 3-401-403, and 3-501, §228.62 of this chapter, and §228.64 of this chapter (relating to Donation of Foods).

(d) Food preparation and protection for excursions.

(1) Except for paragraphs (2) - (4) of this subsection, all food shall be prepared and protected in central preparation facility and meet requirements contained in Food Code, Chapter 3 - Food.

(2) Only commercially prepackaged ready-to-eat foods or ready-to-eat foods that have been prepared and packaged with no cooking at a central preparation facility may be served.

(3) Raw time and temperature control for safety foods (TCS foods) may be cooked on-site if cooked and immediately served.

(4) All food must be stored to protect from contamination in accordance with Food Code, Chapter 3 - Food.

(5) TCS foods that require complex preparation must be served within the first 24 hours of the excursion departure time.

(6) Leftovers. Leftover food shall not be re-heated or re-served.

(e) Warewashing.

(1) Alternative manual warewashing equipment, such as receptacles that substitute for the compartments of a multi-compartment sink, may be used for washing and sanitizing utensils when approved by the regulatory authority.

(2) An outfitter operation without effective facilities for cleaning and sanitizing tableware shall only provide single-service articles for use by food employees and consumers.

(f) Ice usage.

(1) Ice that is used for cooling food may not be used for human consumption.

(2) Ice used for human consumption must be stored in a clean sanitized container that is properly constructed and maintained in good repair.

(g) Potable water.

(1) Potable water shall be used on excursions for human consumption, food preparation, handwashing, and for cleaning and sanitizing utensils and equipment.

(2) Potable water must be stored in a clean sanitized container that is easily cleanable and good condition.

(h) Handwashing.

(1) Handwashing facilities shall include:

(A) a container with a spigot that can be turned on to allow potable, clean, water;

(B) a wastewater container;

(C) soap;

(D) disposable towels; and

(E) a waste receptacle.

(2) Handwashing facilities are not required if the only food items offered are commercially prepackaged foods that are dispensed in their original containers.

(i) Equipment. All equipment and utensils intended for food contact shall be approved for food use.

(j) Thermometers. Thermometers shall be provided, accurate, and accessible during excursions.

(k) Garbage receptacles. Impervious receptacles shall be provided for storage of garbage and refuse.

(l) Certified food protection manager. If food other than prepackaged ready-to-eat food is being served, at least one guide or instructor of the outfitter operation, who is on the excursion, shall successfully complete a food manager's certification course accredited by this department.

(m) Central preparation facility. An outfitter operation must have a central preparation facility as specified in §228.2(20) of this chapter (relating to Definitions).

§228.225. Self-Service Food Market.

(a) Self-service food markets shall comply with the minimum standards of this section.

(b) Self-service food markets shall:

(1) be equipped with 24/7 video surveillance records of consumers viewing, selecting, handling, and purchasing products that identify these consumers. Video surveillance records must be maintained and available for the regulatory authority for a period of 14 calendar days from the date of the video; and

(2) provide information to the regulatory authority as to the responsible party that will be available for routine inspections.

(c) Pre-packaged food sold at a self-service food market shall:

(1) meet the labeling requirements as specified in Food Code, Paragraph 3-201.11(C); and

(2) be tamper evident.

(d) A food specified in Food Code, Paragraphs 3-501.17(A) or (B) or §3-501.18 shall be discarded if it:

(1) exceeds the temperature or time specified in Food Code, Paragraphs 3-501.17(A) and (B), except time that the product is frozen;

(2) is in a container or package that does not bear an expiration date or day; or

(3) is not appropriately marked with a date or day that exceeds the temperature and time combination as specified in Food Code, Paragraphs 3-501.17(A) and (B).

(e) All self-service food market display-units offering refrigerated, time and temperature control for safety foods (TCS foods) shall have an automatic shut-off control or a plan approved by the regulatory authority that prevents the market or market equipment from dispensing food if:

(1) there is a power failure, mechanical failure, or other condition that results in failure of the equipment to maintain food temperatures as specified under Food Code, Chapter 4 - Equipment, Utensils, and Linens; and

(2) where a condition specified in paragraph (1) of this subsection occurs, until the equipment is serviced and restocked with food that has been maintained at temperatures specified in Food Code, Subparts 3-202, 3-401-403, and 3-501, §228.62 of this chapter (relating to Specifications for Receiving), and §228.64 of this chapter (relating to Donation of Foods).

(f) When a condition specified in subsection (e)(1) of this section occurs, the ambient temperature may not exceed five degrees Celsius (41 degrees Fahrenheit), or seven degrees Celsius (45 degrees Fahrenheit) for a unit holding raw shell eggs only, for more than 30 minutes immediately after the display is filled, serviced, or restocked.

(g) All self-service food market display-units offering TCS food, shall be:

(1) equipped with a self-closing door; or

(2) maintained at five degrees Celsius (41 degrees Fahrenheit), or seven degrees Celsius (45 degrees Fahrenheit) for raw shell eggs, if it is an open display unit.

(h) Self-service food markets shall have a sign readily visible from the automated payment kiosk stating:

(1) the name of the business to whom complaints or comments shall be addressed;

(2) the address of the business responsible for the market; and

(3) the responsible business's telephone number and email or web information, when applicable.

(i) When a retail food establishment operating as a self-service food market incorporates the provision in this section, it will not be required to maintain a person in charge onsite as specified in Food Code, Paragraph 2-101.11(A).

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SUBCHAPTER I. COMPLIANCE

25 TAC §§228.241 - 228.257

STATUTORY AUTHORITY

The repeals are authorized by Texas Government Code, §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the efficient enforcement of Texas Health and Safety Code, Chapter 437; and Texas Health and Safety Code, §1001.075, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of health and human services by DSHS and for the administration of Texas Health and Safety Code, Chapter 1001.

The repeals implement Texas Government Code, Chapter 531 and Texas Health and Safety Codes, Chapters 437 and 1001.

§228.241. Use for Intended Purpose.

§228.242. Additional Requirements.

§228.243. Variances.

§228.244. Facility and Operating Plans.

§228.245. Confidentiality, Trade Secrets.

§228.246. Construction Inspection and Approval, Preoperational Inspections.

§228.247. Permit Requirement, Prerequisite for Operation.

§228.248. Conditions of Retention, Responsibilities of the Permit Holder.

§228.249. Inspection Frequency, Performance-based and Risk Based.

§228.250. Competency of Inspectors and Access.

§228.251. Report of Findings.

§228.252. Imminent Health Hazard.

§228.253. Priority Item/Priority Foundation Item, Time Frame for Correction.

§228.254. Core Item Violations, Time Frame for Correction.

§228.255. Examination and Detention of Food.

§228.256. Investigation and Control.

§228.257. Reporting of Communicable Diseases.

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

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25 TAC §§228.241 - 228.246

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The new rules implement Texas Government Code, Chapter 531 and Texas Health and Safety Code, Chapters 437 and 1001.

§228.241. Use for Intended Purpose.

Plans may be required by the regulatory authority for:

(1) the construction of a food establishment;

(2) the conversion of an existing structure for use as a food establishment; or

(3) the remodeling of a food establishment or a change of type of food establishment or food operation, or under the conditions set by the regulatory authority, if the regulatory authority determines that plans and specifications are necessary to ensure compliance with this section.

§228.242. Confidentiality, Trade Secrets.

In accordance with the requirements of the Public Information Act, Texas Government Code, Chapter 552, the regulatory authority shall treat as confidential the information that meets the criteria specified in law for a trade secret and is contained on inspection report forms and in the plans and specifications submitted as specified in Food Code, §8-201.12 and §8-201.14.

§228.243. Construction Inspection and Approval, Preoperational Inspections.

The regulatory authority may conduct one or more preoperational inspections to verify that the food establishment is constructed and equipped in accordance with the approved plans and approved modifications of those plans, has established standard operating procedures as specified in Food Code, Paragraph 8-201.12(E), and is in compliance with this chapter.

§228.244. Performance and Risk Based Inspection.

The regulatory authority shall inspect each food establishment based upon an assessment of the food establishment's history of compliance with this chapter and the potential for causing foodborne illness by evaluating:

(1) past performance, for nonconformance with Food Code or Hazard Analysis Critical Control Point (HACCP) plan requirements that are priority items or priority foundation items;

(2) past performance, for numerous or repeat violations of code or HACCP plan requirements that are core items;

(3) past performance, for complaints investigated and found to be valid;

(4) the hazards associated with the particular foods that are prepared, stored, or served;

(5) the type of operation including the methods and extent of food storage, preparation, and service;

(6) the number of people served;

(7) whether the population served is a highly susceptible population; and

(8) any other risk factors deemed relevant to the operation by the regulatory authority.

§228.245. Competency of Inspectors and Access.

(a) Competency of inspectors. An individual conducting inspections of retail food establishments should be a Registered Professional Sanitarian in Texas or a Sanitarian-in-Training in Texas, as defined in 16 TAC Chapter 119, or should meet the U.S. Food and Drug Administration Voluntary National Retail Food Regulatory Program Standards basic curriculum and field training elements in order to:

(1) assure application of basic scientific principles, including Hazard Analysis Critical Control Point principles of food safety, during inspections;

(2) properly conduct foodborne illness investigations;

(3) assure uniformity in the interpretations of this chapter; and

(4) assure fair and uniform enforcement of this chapter.

(b) Verification and documentation of correction. In the case of temporary food establishments, all priority and priority foundation items must be corrected immediately, and other violations must be corrected within 24 hours or sooner if required by the regulatory authority. If violations are not corrected, the establishment shall immediately cease food operations upon execution of an Emergency Suspension or Closing Order until authorized to resume by the regulatory authority.

§228.246. Investigation and Control.

Removal of restriction or exclusion. The regulatory authority shall release a food employee or conditional employee from restriction or exclusion according to Texas Health and Safety Code, §438.033, and the conditions specified under Food Code, §2-201.13.

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

Filed with the Office of the Secretary of State on March 19, 2021.

TRD-202101152
Barbara L. Klein
General Counsel
Department of State Health Services
Earliest possible date of adoption: May 2, 2021
For further information, please call: (512) 834-6753

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SUBCHAPTER J. PRIVATE WATER SYSTEMS

25 TAC §§228.271 - 228.278

STATUTORY AUTHORITY

The repeals are authorized by Texas Government Code, §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the efficient enforcement of Texas Health and Safety Code, Chapter 437; and Texas Health and Safety Code, §1001.075, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of health and human services by DSHS and for the administration of Texas Health and Safety Code, Chapter 1001.

The repeals implement Texas Government Code, Chapter 531 and Texas Health and Safety Code, Chapters 437 and 1001.

§228.271. Water Supply and Pressure.
§228.272. Water Quality.
§228.273. Backflow Prevention.
§228.274. Disinfection of New or Repaired Water System Facilities.
§228.275. Flushing of Water System Mains.
§228.276. Collection System Location.
§228.277. Well Logs.
§228.278. Interconnection.

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

Filed with the Office of the Secretary of State on March 19, 2021.

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Barbara L. Klein
General Counsel
Department of State Health Services
Earliest possible date of adoption: May 2, 2021
For further information, please call: (512) 834-6753

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CHAPTER 289. RADIATION CONTROL
SUBCHAPTER E. REGISTRATION REGULATIONS

25 TAC §289.226

The Executive Commissioner of the Texas Health and Human Services Commission (HHSC), on behalf of the Department of State Health Services (DSHS), proposes an amendment to §289.226, concerning Registration of Radiation Machine Use and Services.

BACKGROUND AND PURPOSE

The purpose of the amendment is to correct rule citation references and define registrant responsibilities. Other changes to §289.226 include clarifying rule requirements as suggested by staff and stakeholders and updating terminology. The amendment clarifies qualifications for radiation safety officers (RSOs), requires RSOs to review operating and safety procedures at least annually, and clarifies the service company responsibility to perform equipment performance evaluations on radiation machines within 30 days of installation or repair that affects radiation output. In addition, the amendment adds safety requirements to Operating and Safety Procedures and strengthens the requirements for quality control of digital imaging. Minor editorial changes were made to create less ambiguity within the amendment.

Texas Government Code, §2001.039, requires that each state agency review and consider for re-adoption each rule adopted by that agency pursuant to the Texas Government Code, Chapter 2001 (Administrative Procedure Act). Section 289.226 has been reviewed and DSHS has determined that the reasons for adopting the section continue to exist because a rule on this subject is needed to protect public health and safety and to fulfill DSHS's statutory responsibilities as the state's Radiation Control Agency.

SECTION-BY-SECTION SUMMARY

The term "department" replaces the former term "agency" throughout §289.226 for consistency with the use of "department" in 25 Texas Administrative Code.

Amended §289.226(a)(2) modifies the requirements for the registration of person using radiation machines. Subsection (a)(2)(A) adds a requirement that no person can use a radiation machine unless they have a certificate of registration.

Amended §289.226(b)(11)(B) adds the measurement of air kerma for a machine registered under §289.229 as a service that requires registration as a service company.

Amended §289.226(b)(11)(E) clarifies that any company that must energize a radiation machine for demonstration or sale of radiation machines or image acquisition systems must register as a service company.

Amended §289.226(b)(16) defines the term "veterinary-use" for this section.

Amended §289.226(c)(1) adds a prohibition that no person shall be exposed to useful beam for training, demonstration, or other non-healing arts purposes.

Amended §289.226(c)(3) adds a prohibition that radiation machines must be designated for human-use or veterinary-use but cannot be designated as both, unless performing research or approval is granted by the agency.

Amended §289.226(d)(8) adds an exemption for bone densitometry systems from the requirement to perform equipment performance evaluations.

Amended §289.226(e)(3)(B) adds qualifications for approval of a RSO according to facility types.

Amended §289.226(e)(3)(B)(i)(II) adds qualifications for approval of a non-practitioner to become an RSO.

Amended §289.226(e)(3)(B)(i)(III) adds qualifications for approval of a person to become an RSO without being a licensed practitioner or having radiation machine-related credentials.

Amended §289.226(e)(3)(B)(i)(III)(-a-) adds the list of credentials that a person must have in order to become an RSO without being a licensed practitioner or having radiation machine-related credentials.

Amended §289.226(e)(3)(B)(i)(III)(-b-) adds additional documentation that must be provided to qualify as a non-practitioner RSO without radiation machine-related credentials.

Amended §289.226(e)(3)(B)(ii) requires academic institutions or research and development facilities to have RSOs who are faculty or staff members with a bachelor's degree or higher in a

radiation-related field and at least two years of supervised experience in the use of radiation machines.

Amended §289.226(e)(3)(B)(ii)(I) and (II) lists documentation required for §289.226(e)(3)(B)(ii).

Amended §289.226(e)(3)(E) adds stipulation that DSHS may determine that a person, who otherwise meets the RSO requirements of this section, may be unqualified based on the person's regulatory compliance history.

Amended §289.226(e)(5) removes laser, laser services, laser hair removal facilities, laser hair removal training programs, and laser hair removal individuals since these programs have moved to the Texas Department of Licensing and Regulation.

Amended §289.226(e)(7) clarifies the reference for registration fees that can be found at §289.204 of this title.

Amended §289.226(e)(8)(B) clarifies that applications must file an assumed names certificate with the Texas Secretary of State instead of with the county clerk in the county where the business is located.

Amended §289.226(f)(1)(B) adds electronic brachytherapy machines to the list of accelerators that must apply for and receive a certificate of registration before using the machine.

Amended §289.226(f)(5) clarifies documentation and credentials required for registration of accelerators, therapeutic radiation machines, and electronic brachytherapy devices used on humans.

Amended §289.226(h)(2)(G) removes the requirement to provide training data for approval of registration for healing arts screening.

Amended §289.226(h)(3) adds the requirement that screening standards and procedures shall meet national standards such as those recommended by the American College of Radiology or other national standards.

Amended §289.226(i)(2) adds reference to §289.255 of this title for industrial radiographic operations.

Amended §289.226(i)(3) adds that the applicant must receive a certificate of registration from the agency before operating industrial radiographic machines.

Amended §289.226(m)(3) adds electronic brachytherapy machines to the list of machines that require agency approval before using the machine.

Amended §289.226(m)(13)(C) adds that companies who provide demonstrations and sales of radiation machines may never expose individuals to a useful beam except for healing arts purposes and unless such exposure has been specifically and individually ordered by a licensed practitioner of the healing arts.

Amended §289.226(m)(13)(C)(i) - (iii) adds specific examples in which deliberate exposure of humans to the useful beam is strictly prohibited.

Amended §289.226(m)(13)(E) states that a service company that demonstrates radiation machines for healing arts purposes must perform and document machine testing to meet the requirements of §289.227 of this title.

Amended §289.226(n)(1)(A)(i) revises the requirement that RSOs must review the chapter and policies and procedures at an interval not to exceed 12 months to ensure procedures are current and conform with the chapter.

Amended §289.226(n)(1)(A)(ii) adds that RSOs are responsible for the facility's compliance with the rules.

Amended §289.226(n)(1)(E) makes the RSO responsible to ensure corrective actions for violations issued by the agency are implemented to avoid repeat violations.

Amended §289.226(n)(3) adds that the RSO shall make entries of the dosimetry monitoring records from subsection (n)(1)(B) of this section at intervals not to exceed 30 days after receipt of a monitoring report.

Amended §289.226(o)(5)(B) corrects rule citation references.

Amended §289.226(o)(7)(D) adds requirements that a radiation machine must have the entrance exposure re-tested after the machine has been repaired or adjusted by a registered service company.

Amended §289.226(o)(7)(E) adds that the licensed medical physicist (LMP) or service company performing equipment performance evaluations (EPEs) must submit results to the facility within 30 days after completion of testing.

Amended §289.226(o)(7)(E)(i) - (ix) adds documentation that must be included on an EPE report.

Amended §289.226(o)(7)(F) adds that an LMP or service company must maintain records of EPEs according to the length of time the facility is required to maintain records.

Amended §289.226(o)(7)(G)(i) - (ii) adds that dosimetry system available for use must be calibrated by the National Institute for Standards and Technology or by an American Association of Physicists in Medicine Accredited Dosimetry Calibration Laboratory and the calibration must have been completed within the previous 24 months and after any servicing that may have affected the system calibration.

Amended §289.226(t)(1)(C) adds RSO qualifications to the list of documents required for approval of reciprocal recognition of out-of-state certificates of registration.

Amended Figure §289.226(v)(1) to include record retention requirements that are currently in other sections of 25 Texas Administrative Code Chapter 289.

FISCAL NOTE

Donna Sheppard, Chief Financial Officer, has determined that for each year of the first five years that the rule will be in effect, enforcing or administering the rule does not have foreseeable implications relating to costs or revenues of state or local governments.

GOVERNMENT GROWTH IMPACT STATEMENT

DSHS has determined that during the first five years that the rule will be in effect:

(1) the proposed rule will not create or eliminate a government program;

(2) implementation of the proposed rule will not affect the number of DSHS employee positions;

(3) implementation of the proposed rule will result in no assumed change in future legislative appropriations;

(4) the proposed rule will not affect fees paid to DSHS;

(5) the proposed rule will not create a new rule;

(6) the proposed rule will expand an existing rule;

(7) the proposed rule will not change the number of individuals subject to the rule; and

(8) the proposed rule will not affect the state's economy.

SMALL BUSINESS, MICRO-BUSINESS, AND RURAL COMMUNITY IMPACT ANALYSIS

Donna Sheppard has also determined that there will be no significant adverse economic impact on small businesses, micro-businesses, or rural communities required to comply with the section as proposed. The rule does not impose any additional costs on small businesses, micro-businesses, or rural communities that are required to comply with the rule. The proposed rule will not affect fees to businesses. The proposed rule will not result in additional work for DSHS employees or other public entities.

LOCAL EMPLOYMENT IMPACT

The proposed rule will not affect a local economy.

COSTS TO REGULATED PERSONS

Texas Government Code, §2001.0045 does not apply to this rule because this rule is necessary to protect the health, safety, and welfare of the residents of Texas.

PUBLIC BENEFIT AND COST

Stephen Pahl, Associate Commissioner, Consumer Protection Division, has determined that for each year of the first five years the rule is in effect, the public will benefit from adoption of the section. The public benefit anticipated as the result of enforcing or administering the section is to ensure continued enhanced protection of the public, patients, workers, and the environment from unnecessary exposure to radiation by ensuring that the rule is clear and specific.

Donna Sheppard has also determined that for the first five years the rule is in effect, there are no anticipated economic costs to persons who are required to comply with the proposed rule.

TAKING IMPACT ASSESSMENT

DSHS has determined that the proposal does not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, do not constitute a taking under Texas Government Code, §2007.043.

PUBLIC COMMENT

Written comments on the proposal may be submitted to Brian Vamvakias, Radiation Unit Manager, Policy, Standards, and Quality Assurance Section, Consumer Protection Division, DSHS, Mail Code 1987, P.O. Box 149347, Austin, Texas 78714-9347; Exchange Building, 8407 Wall Street, Austin, Texas 78754, (512) 834-6655 or by email to CPDRuleComments@dshs.texas.gov.

To be considered, comments must be submitted no later than 31 days after the date of this issue of the *Texas Register.* Comments must be: (1) postmarked or shipped before the last day of the comment period; (2) hand-delivered before 5:00 p.m. on the last working day of the comment period; or (3) emailed before midnight on the last day of the comment period. If last day to submit comments falls on a holiday, comments must be postmarked, shipped, or emailed before midnight on the following business day to be accepted. When emailing comments, please indicate "Comments on Proposed Rule 20R029" in the subject line.

STATUTORY AUTHORITY

The amendment is authorized by Texas Health and Safety Code, Chapter 401 (the Texas Radiation Control Act), which provides for DSHS radiation control rules and regulatory program to be compatible with federal standards and regulation; §401.051, which provides the required authority to adopt rules and guidelines relating to the control of sources of radiation; §401.064, which provides for the authority to adopt rules related to inspection of x-ray equipment; §401.101, providing for DSHS registration of facilities possessing sources of radiation; Chapter 401, Subchapter J, which authorizes enforcement of the Act; and Texas Government Code, §531.0055; and Texas Health and Safety Code, §1001.075, which authorizes the Executive Commissioner of HHSC to adopt rules and policies for the operation and provision of health and human services by DSHS and for the administration of Texas Health and Safety Code, Chapter 1001. The review of the rule implements Texas Government Code, §2001.039, regarding review of existing rules.

The amendment will implement Texas Health and Safety Code, Chapters 401 and 1001; and Texas Government Code, Chapter 531.

§289.226. Registration of Radiation Machine Use and Services.

(a) Purpose.

(1) This section provides for the registration of persons using radiation machines and persons who are in the business of providing radiation machine services.

(2) Requirements for the registration of persons using radiation machines.

(A) No person shall use radiation machines except as authorized in a certificate of registration issued by the Department of State Health Services (department) per the requirements of this section.

(B) A person who receives, possesses, uses, owns, or acquires radiation machines before receiving a certificate of registration is subject to the requirements of this chapter.

[~~(2) A person who receives, possesses, uses, owns, or acquires radiation machines prior to receiving a certificate of registration is subject to the requirements of this chapter.~~]

(b) Scope.

(1) In addition to the requirements of this section, all registrants are subject to the requirements of:

(A) §289.203 of this title (relating to Notices, Instructions, and Reports to Workers; Inspections); [;]

(B) §289.204 of this title (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services); [;]

(C) §289.205 of this title (relating to Hearing and Enforcement Procedures); [;] and

(D) §289.231 of this title (relating to General Provisions and Standards for Protection Against Machine-Produced Radiation).

(2) Registrants using radiation machines in the healing arts are also subject to the requirements of §289.227 of this title (relating to Use of Radiation Machines in the Healing Arts). Morgues, educational facilities, and forensic medicine or investigations utilizing radiation machines for non-human use are subject to the specific requirements of §289.227 of this title.

(3) Registrants using analytical and other industrial radiation machines, such as x-ray equipment used for cathodoluminescence, ion implantation, gauging, or electron beam welding, are subject to the

requirements of §289.228 of this title (relating to Radiation Safety Requirements for Industrial Radiation Machines).

(4) Registrants using accelerators, therapeutic radiation machines, simulators, and electronic brachytherapy devices are also subject to the requirements of §289.229 of this title (relating to Radiation Safety Requirements for Accelerators, Therapeutic Radiation Machines, Simulators, and Electronic Brachytherapy Devices).

(5) Registrants using mammography radiation machines are also subject to the requirements of §289.230 of this title (relating to Certification of Mammography Systems and Mammography Machines Used for Interventional Breast Radiography) and §289.234 of this title (relating to Mammography Accreditation).

(6) Registrants using radiation machines in industrial radiographic operations are also subject to the requirements of §289.255 of this title (relating to Radiation Safety Requirements and Licensing and Registration Procedures for Industrial Radiography).

(7) Registrants using radiation machines in dental medicine [~~dental radiation machines~~] are subject to the requirements of §289.232 of this title (relating to Radiation Control Regulations for Dental Radiation Machines).

(8) Registrants using radiation machines in veterinary medicine are subject to the requirements of §289.233 of this title (relating to Radiation Control Regulations for Radiation Machines Used in Veterinary Medicine).

(9) Registrants using laser radiation machines [~~or performing laser services~~] are subject to the requirements of §289.301 of this title (relating to Registration and Radiation Safety Requirements for Lasers and Intense-Pulsed Light Devices) [~~or the requirements of §289.302 of this title (relating to Registration and Radiation Safety Requirements for Use of Laser Hair Removal Devices)~~].

(10) To determine compliance with the requirements in this chapter for radiation machines [~~used on humans~~], all radiation air kerma rate [~~exposure rate (air kerma rate)~~] or dose measurements for fluoroscopy or computed tomography radiation machines shall be performed by a licensed medical physicist with a specialty in diagnostic medical physics.

(11) For purposes of this section, radiation services include [~~but are not limited to~~]:

(A) measurement of air kerma rate or dose measurements on radiation machines that are not for human use;

(B) measurement of air kerma for human-use, general radiographic and special purpose radiation machines, as defined in §289.227 and §289.229 of this title, by or under the supervision of a licensed medical physicist;

[~~(A) radiation machines that are not for human use, performance of exposure rate (air kerma rate) or dose measurements;~~]

[~~(B) radiation machines for human use, collecting entrance exposure (air kerma) data for general radiographic and special purpose radiation machines, as defined in §289.227(e) of this title, by or under the supervision of a licensed medical physicist;~~]

(C) [~~radiation machines for human use,~~] performance of services specified in paragraph (10) of this subsection or services requiring a licensed medical physicist as specified in §289.227(e) and §289.229 of this title on radiation machines for human use;

(D) presentation of department-accepted [~~agency-accepted~~] training courses that are specifically required by this chapter;

(E) demonstration and sale of radiation machines or imaging acquisition systems that require the individual to operate a radiation machine or cause a radiation machine to be energized [~~that require the individual to operate or cause a radiation machine to be operated in order to demonstrate or sell~~];

(F) assembly, installation or repair of a radiation machine to ensure it [~~a radiation machine~~] is operating according to manufacturer's specifications;

(G) completion of equipment performance evaluations (EPE) on dental radiation machines and [~~on~~] machines used in veterinary medicine; and

(H) provision of [~~providing~~] radiation machines to a facility for limited [~~time~~] periods.

(12) For purposes of this section, a person providing the services described in paragraph (11)(H) of this subsection is a provider of equipment.

(13) For purposes of this section, a practitioner of the healing arts is a person licensed to practice healing arts by either the Texas Medical Board as a physician, the Texas Board of Chiropractic Examiners, or the Texas State Board of Podiatric Medical Examiners.

(14) For purposes of this section, a physician is an individual licensed by the Texas Medical Board.

(15) For purposes of this section, a certified physician is a physician licensed by the Texas Medical Board and certified in radiation oncology or therapeutic radiology.

(16) For purposes of this section, veterinary-use is the use of a radiation machine for the practice of veterinary medicine as defined by Texas Occupations Code Chapter 801. Animal research is not considered veterinary-use.

(17) [~~(16)~~] This section does not apply to an entity under the jurisdiction of the federal government.

(c) Prohibitions.

(1) No person shall cause the operation of a radiation machine that results in exposure of an individual to the useful beam [~~expose an individual to radiation~~] for training, demonstration, or other non-healing arts purposes.

(2) No person shall use radiation machines or perform radiation machine services except as authorized in a certificate of registration issued by the department per [~~agency in accordance with~~] the requirements of this section.

(3) Radiation machines shall be designated for human-use or veterinary-use but shall not be designated for both unless one of the following conditions are met:

(A) the machine use is for human research conducted per subsection (u) of this section; or

(B) the facility has applied for and received written authorization from the department.

(d) Exemptions.

(1) Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of this section, provided that the dose equivalent rate averaged over an area of 10 square centimeters (cm^2) does not exceed 0.5 millirem per hour (mrem/hr)(0.005 mSv per hour (mSv/hr)) at 5 centimeters (cm) from any accessible surface of such equipment. The production, testing, or factory servicing of such equipment shall not be exempt.

(2) Radiation machines in transit or [~~in~~] storage incident to transit are exempt from the requirements of this section. This exemption does not apply to the providers of radiation machines for mobile services.

(3) Facilities that have placed all radiation machines in storage, including on-site storage secured from unauthorized use or removal, and have notified the department [~~agency~~] in writing, are exempt from the requirements of this section. This exemption is void if any radiation machine is energized resulting in the production of radiation. Before [~~Prior to~~] resuming use of the machine(s) for human use, the machine shall meet all requirements of this section.

(4) Inoperable radiation machines are exempt from the requirements of this section. For [~~the purposes of~~] this section, an inoperable radiation machine means a radiation machine that cannot be energized when connected to a power supply without repair or modification.

(5) Domestic television receivers, video display terminals, transmission microscopes, and electron microscopes, including the servicing of such devices, are exempt from the requirements of this section.

(6) A person that takes possession of a radiation machine as the result of foreclosure, bankruptcy, or other default of payment may possess the machine without registering it. If the machine is energized, it shall be under the supervision of a person registered per [~~in accordance with~~] this section and shall be energized only to demonstrate that the machine is operable for sale, lease, or transfer purposes.

(7) Facilities, including academic institutions and research or development facilities, registered for the use of radiation machines are exempt from the registration requirements of subsection (j) of this section, regarding radiation services, to the extent that their personnel perform radiation services only for the registrant by whom they are employed.

(8) Bone densitometry machines used by, or under the supervision of, a licensed physician, are exempt from equipment performance evaluations.

(e) General requirements for application for registration.

(1) Application for registration shall be completed on forms prescribed by the department [~~agency~~] and shall contain all the information required by the form and accompanying instructions. For initial registrations with multiple use locations, a separate application RC Form 226-2 shall be completed for each use location under the registration.

(2) A radiation safety officer (RSO) shall be designated on each application form. The qualifications of that individual shall be submitted to the department [~~agency~~] with the application. The RSO shall meet the applicable qualifications specified in paragraph (3) of this subsection and carry out the responsibilities of subsection (n) of this section.

(3) Qualifications for RSOs for registrants [~~(except for industrial radiography)~~].

(A) All RSOs [~~and laser safety officers~~] shall meet the following general qualifications in addition to qualifications in specific categories:

(i) knowledge of potential radiation hazards and emergency precautions; and

(ii) completed educational courses related to ionizing radiation safety or a radiation safety officer course; or

(iii) experience in the use and familiarity of the type of equipment used.

(B) Specific qualifications for RSOs by the facility type are as follows.

(i) RSOs for healing arts facilities shall meet the following qualifications:

(I) practitioner RSOs shall submit documentation of their licensing board number;

(II) qualifications for a non-practitioner RSO with radiation machine-related credentials, and the following credentials will be accepted for an RSO who is not a practitioner:

(-a-) evidence of a valid general certificate issued under the Medical Radiologic Technologist Certification Act, Texas Occupations Code, Chapter 601, and at least two years of supervised radiation safety experience or supervised use of radiation machines;

(-b-) evidence of a valid limited certificate issued under the Medical Radiologic Technologist Certification Act, Texas Occupations Code, Chapter 601, and at least four years of supervised radiation safety experience or supervised use of radiation machines;

(-c-) evidence of registry by the American Registry of Radiologic Technologists (ARRT) or the American Registry of Clinical Radiologic Technologists (ARCRT) and at least two years of supervised radiation safety experience or supervised use of radiation machines;

(-d-) evidence of associate degree in radiologic technology, health physics, or nuclear technology, and at least two years of supervised radiation safety experience or supervised use of radiation machines;

(-e-) for radiation therapy facilities, evidence of registry by the ARRT or ARCRT and at least four years of supervised radiation-related experience or supervised use of radiation therapy machines; or

(-f-) evidence of a current Texas license under the Medical Physics Practice Act, Texas Occupations Code, Chapter 602, in one or more of the following appropriate specialties:

(-1-) medical health physics, diagnostic medical physics, or nuclear medical physics for diagnostic x-ray facilities; or

(-2-) medical health physics or therapeutic medical physics for radiation therapy facilities; or

(III) qualification for a non-practitioner RSO without radiation machine-related credentials, and an RSO who is not a practitioner and who does not have radiation machine-related credentials must meet the following criteria:

(-a-) credentials:

(-1-) evidence of registration with the Texas Board of Nursing as a registered nurse and at least two years of supervised experience in the use of radiation machines in their respective specialty;

(-2-) evidence of registration with the Texas Physician Assistant Board and at least two years of supervised experience in the use of radiation machines in their respective specialty; or

(-3-) evidence of bachelor's or higher degree in radiologic technology, health physics, or nuclear technology and at least two years of supervised experience in the use of radiation machines; and

(-b-) additional documentation for a non-practitioner RSO without radiation machine-related credentials, and the following documentation must be provided to be qualified:

(-1-) an attestation by a physician or qualified department director describing the radiation safety experience and performance of the RSO responsibilities listed in subsection (n) of this section, as applicable, and attestation must include that the RSO has achieved a level of radiation safety knowledge sufficient to function independently as RSO for the medical use for which they are applying; and

(-2-) documentation of an accredited radiation safety or radiation machine course completion, and the course must be at least 24 credit hours and include the principles of image processing, radiation protections, dose optimization and reduction; biological effects of ionizing radiation; radiology quality control and improvement; and review of Texas Regulations related to radiation as applicable.

(ii) Academic institutions or research and development facilities shall have RSOs who are faculty or staff members with a bachelor's degree or higher in a radiation-related field and at least two years of supervised experience in the use of radiation machines and the following documentation is also required:

(I) an attestation by a physician or qualified department director describing the radiation safety experience and performance of the RSO responsibilities listed in subsection (n) of this section, as applicable, and attestation must include that the RSO has achieved a level of radiation safety knowledge sufficient to function independently as RSO for the medical use for which they are applying.

(II) documentation that the individual has satisfactorily completed 40 hours of education related to safe use of radiation machines from an accredited institution.

[~~(B) Specific qualifications for RSOs by facility are as follows.~~]

[~~(i)~~ ~~Healing arts facilities shall have:~~]

[~~(I)~~ ~~a practitioner RSO with documentation of licensing board number; or~~]

[~~(II)~~ ~~a non-practitioner RSO with at least one of the following:~~]

[~~(-a-) evidence of a valid general certificate issued under the Medical Radiologic Technologist Certification Act, Texas Occupations Code, Chapter 601, and at least 2 years of supervised experience and/or supervised use of radiation machines;~~]

[~~(-b-) evidence of a valid limited certificate issued under the Medical Radiologic Technologist Certification Act, Texas Occupations Code, Chapter 601, and at least 4 years of supervised experience and/or supervised use of radiation machines;~~]

[~~(-c-) evidence of registry by the American Registry of Radiologic Technologists (ARRT) or the American Registry of Clinical Radiologic Technologists (ARCRT) and at least 2 years of supervised experience and/or supervised use of radiation machines;~~]

[~~(-d-) evidence of associate degree in radiologic technology, health physics, or nuclear technology, and at least 2 years of supervised experience and/or supervised use of radiation machines;~~]

[~~(-e-) evidence of registration with the Texas Board of Nursing as a Registered Nurse and at least 2 years of supervised experience and/or supervised use of radiation machines in the respective specialty;~~]

[~~(-f-) evidence of registration with the Texas Physician Assistant Board, and at least 2 years of supervised use of radiation machines in the respective specialty;~~]

[~~(-g-) for radiation therapy facilities, evidence of registry by the ARRT or ARCRT and at least 4 years of supervised experience and/or supervised use of radiation therapy machines;~~]

[~~(-h-) evidence of bachelor's (or higher) degree in radiologic technology, health physics, or nuclear technology and at least 2 years of supervised experience and/or supervised use of radiation machines; or~~]

[~~(-i-) evidence of a current Texas license under the Medical Physics Practice Act, Texas Occupations Code, Chapter 602, in one or more of the following appropriate specialties:~~]

[~~(-1-) medical health physics, diagnostic medical physics, or nuclear medical physics for diagnostic x-ray facilities; or~~]

[~~(-2-) medical health physics or therapeutic medical physics for radiation therapy facilities.~~]

[~~(ii)~~ ~~Academic institutions and/or research and development facilities shall have RSOs who are faculty or staff members in radiation protection, radiation engineering, or related disciplines. This individual may also serve as the RSO over the healing arts section of the facility.~~]

(iii) Industrial radiography operations shall have an RSO who meets the requirements of §289.255(e)(4)(B) of this title.

(C) The RSO identified on a certificate of registration issued before September 1, 1993, need not comply with the training requirements in this subsection.

(D) The RSO for an application for registration of an electronic brachytherapy device shall meet the qualifications of this subsection and shall carry out the responsibilities of subsection (n) of this section.

(E) The department may determine that a person who otherwise meets the RSO qualifications specified in this section is unqualified to be named as the RSO, based on the person's history with ensuring a facility's compliance with the Act and rules of this chapter.

(4) Any time after the filing of the original application, the department [~~agency~~] may require additional information to determine if the certificate of registration should be issued or denied.

(5) An application for a certificate of registration may include a request for a certificate of registration authorizing one or more activities or use locations. Applications for certification of mammography systems[~~, lasers, laser services, laser hair removal facilities, laser hair removal training programs, and laser hair removal individuals~~] shall be made separately.

(6) Applications and documents submitted to the department [~~agency~~] may be made available for public inspection except that the department [~~agency~~] may withhold any document or part thereof from public inspection per [~~in accordance with~~] §289.231(aa) of this title.

(7) Each application for a certificate of registration shall be accompanied by the fee prescribed in §289.204 of this title. [~~An application for a certificate of registration for an electronic brachytherapy device shall be accompanied by the fee prescribed in Figure: 25 TAC §289.204(j), category (3) for other therapeutic radiation machines.~~]

(8) Each application shall be accompanied by a completed RC Form 226-1 (Business Information Form) that shall contain the le-

gal name of the entity or business. Unless exempt per [~~in accordance with~~] the Business and Commerce Code, Chapter 71, the applicant shall:

(A) be authorized to conduct business in the State of Texas as listed on the Texas Secretary of State (SOS) web site; and

(B) file an assumed name certificate with the Texas SOS if using an assumed name in their application[~~, and/or the office of the county clerk in the county where the business is located~~].

(f) Application for registration for human use of radiation machines.

(1) In addition to the requirements of subsection (e) of this section, each applicant shall comply with the following.

(A) Each person having a radiation machine used in the healing arts shall apply for registration with the department [~~agency~~] within 30 days after beginning use of the radiation machine, except for mobile services that shall be registered per [~~in accordance with~~] subsection (g) of this section, and healing arts screening that shall be approved per [~~in accordance with~~] subsection (h) of this section.

(B) Each person having an accelerator, [~~or~~] therapeutic radiation machine, or electronic brachytherapy device [~~capable of operating at or above 1 million electron volts (MeV)~~] shall apply for and receive a certificate of registration from the department [~~agency~~] before using the accelerator [~~for human use~~]. A person may energize the accelerator for purposes of installation and acceptance testing before receiving a certificate of registration from the department [~~agency~~].

[~~(C) Each person having a simulator and/or therapeutic radiation machine capable of operating below 1 MeV for human use shall apply for registration with the agency within 30 days of energizing the equipment.~~]

(2) The applicant shall ensure that radiation machines are operated by individuals qualified by [~~reason of~~] training and experience to use the radiation machines [~~machine~~] for the purpose requested per [~~in accordance with~~] this section in such a manner as to minimize danger to occupational and public health and safety.

(3) An application for healing arts shall be signed by a licensed practitioner. The signature of the administrator, president, or chief executive officer will be accepted instead [~~in lieu~~] of a licensed practitioner's signature if the facility has more than one licensed practitioner who may direct the operation of radiation machines. The application shall also be signed by the RSO.

(4) An application for accelerators or therapeutic radiation machines, including electronic brachytherapy devices, for human use, shall be signed by a physician licensed by the Texas Medical Board. The signature of the administrator, president, or chief executive officer will be accepted instead [~~in lieu~~] of a physician's signature if the facility has more than one physician who may direct the operation of radiation machines. The application shall also be signed by the RSO.

(5) Each applicant for accelerators, therapeutic radiation machines, and electronic brachytherapy devices, shall submit:

(A) operating and safety procedures as described in §289.229(h)(1)(G) of this title;

(B) credentials:

(i) units operating above 1 MeV and electronic brachytherapy devices shall submit credentials for a Board-Certified Radiation Oncologist; or

(ii) units under 1 MeV shall submit credentials for a Board-Certified Dermatologist or Board-Certified Radiation Oncologist;

(C) a copy of the most current record of surveys, calculations, and quality assurance checks on each device; and

(D) a floor plan of the physical facility.

[~~(5) Each applicant for accelerators or therapeutic radiation machines, other than electronic brachytherapy devices, shall submit:~~]

[~~(A) operating and safety procedures as described in §289.229(h)(1)(G) of this title; and~~]

[~~(B) a description of the proposed facilities.~~]

[~~(6) Each person having an electronic brachytherapy device shall apply for and receive a certificate of registration from the agency before using the device for human use. An application for an electronic brachytherapy device shall include:~~]

[~~(A) a list identifying the radiation safety officer, all certified physicians (except visiting certified physicians), licensed medical physicists, and qualified operators, with documentation of training and education in accordance with §289.229(h)(1)(D) and (E) of this title;~~]

[~~(B) a current copy of the quality assurance program in accordance with §289.229(h)(1)(F) of this title;~~]

[~~(C) a copy of the most current record of surveys, calculations, and quality assurance checks on each device;~~]

[~~(D) a copy of the device manufacturer's United States Food and Drug Administration certification;~~]

[~~(E) a copy of the operating and safety procedures as described in §289.229(h)(1)(G) of this title; and~~]

[~~(F) a description of the proposed facilities showing how the requirements of §289.229(k) of this title are to be met. The description of the proposed facilities shall also include:~~]

~~(i)~~ ~~a diagram of the physical facility showing the location of the electronic brachytherapy treatment rooms;~~]

~~(ii)~~ ~~an indication whether the facility is a new structure or a modification to an existing structure; and~~]

~~(iii)~~ ~~the type and thickness of the portable shielding if used and a procedure demonstrating the use of the shielding prior to treatment.~~]

(g) Application for registration of mobile service operations.

(1) In addition to the requirements of subsections (e) and (f) of this section or §289.230 of this title, as applicable, each applicant shall apply for and receive authorization from the department [~~agency~~] before beginning mobile service operations.

(2) The following shall be submitted:

(A) an established main location where the machine(s), records, etc. will be maintained for inspection. This shall be a street address, not a post office box number;

(B) a sketch or description of the normal configuration of each radiation machine's use, including the operator's position and any ancillary personnel's location during exposures. If a mobile van is used with a fixed machine inside, furnish the floor plan indicating protective shielding and the operator's position; and

(C) a current copy of the applicant's operating and safety procedures regarding radiological practices for the protection of patients, operators, employees, and the general public.

(h) Application for registration of healing arts screening.

(1) In addition to the requirements of subsections (e) and (f) of this section, each applicant shall apply for and receive authorization for healing arts screening before initiating a screening program.

(2) Persons requesting approval from the department [~~agency~~] for healing arts screening programs shall submit:

(A) name and address of the applicant;

(B) diseases or conditions for which the x-ray examinations are to be used in diagnoses;

(C) a detailed description of the x-ray examinations proposed in the screening program;

(D) a description of the population to be examined in the screening program, for example, age, sex, physical condition, and other appropriate information;

(E) for mobile screening operations, location(s) where radiation machines are maintained;

(F) operating and safety procedures as follows:

(i) for all radiation machines (except bone densitometers) to include:

(I) an evaluation of the radiation machines to be used in the screening program;

(II) documentation that the evaluation was performed by a licensed medical physicist with a specialty in diagnostic medical physics;

(III) the evaluation shall show that the machines satisfy all requirements of this chapter;

(ii) for bone densitometers, the manufacturer's evaluation of the radiation machine(s) to be used in the screening program;

~~[(G) training data to include:]~~

~~*f(i)* [the qualifications of each individual who will be operating the radiation machine(s);]~~

~~*f(ii)* the name and address of the physician licensed in Texas who will interpret the radiographs; and]~~

(G) [~~(II)~~] documentation for verification of the following procedures:

(i) a method of recommending a means of selecting a physician for patients who do not have a physician;

(ii) a description of the procedures to be used in advising the individuals screened and their physicians of the results of the screening procedure and any further medical needs indicated; and

(iii) a description of the procedures for the retention or disposition of the radiographs and other records about [~~pertaining to~~] the x-ray examinations.

(3) Screening standards/procedures shall meet national standards such as the American College of Radiology or other national standards.

(i) Application for registration of radiation machines for non-human use, including use in morgues, forensic medicine or investigations, and educational facilities.

(1) In addition to the requirements of subsection (e) of this section, each applicant shall comply with the following.

(A) Each person having an accelerator for non-human use shall apply for and receive a certificate of registration from the department [~~agency~~] before beginning the use of the accelerator. A person may energize the accelerator for purposes of installation and testing before receiving a certificate of registration from the department [~~agency~~].

(B) Each person having an accelerator for non-human use shall submit:

(i) operating and safety procedures as described in §289.229(f)(3)(B) of this title; and

(ii) a description of the applicant's proposed facilities per [~~in accordance with~~] §289.229(f)(2) and (f)(3)(A), (D) and (E) of this title.

(2) Each person having a radiation machine for non-human use, other than those specified in paragraph (1)(A) of this subsection and those used for industrial radiographic operations as defined in §289.255 of this title, shall apply for registration with the department [~~agency~~] within 30 days after beginning use of the machine.

(3) Each applicant for use of radiation machines in industrial radiographic operations shall submit the information required in §289.255(t)(1) of this title and receive a certificate of registration from the department before beginning use of the machine(s).

(4) An application for the uses specified in this subsection shall be signed by the applicant, registrant, or a person duly authorized to act for and on the applicant's or registrant's behalf. The application shall also be signed by the RSO.

(j) Application for registration of radiation machine services.

(1) In addition to the requirements of subsection (e) of this section, each applicant shall comply with the following.

(A) Each person who intends to provide radiation services described in subsection (b)(11) of this section shall apply for and receive a certificate of registration from the department [~~agency~~] before providing the service.

(B) An application for radiation services shall be signed by the applicant or registrant or a person duly authorized to act for and on the applicant's or registrant's behalf. The application shall also be signed by the RSO.

(2) The applicant shall document the qualifications of the specific training and experience that qualifies each individual to perform the service as follows:

(A) for individuals performing assembly, installation, or repair of radiation machines in subsection (b)(11)(F) of this section, document the qualifications listed in paragraph (5) of this subsection;

(B) for individuals performing the services specified in subsection (b)(10) and (11)(C) of this section, obtain a copy of the individual's license from the Texas Board of Licensure for Professional Medical Physicists; and

(C) for all other services, document the qualifications listed in paragraph (5) of this subsection.

(3) No person shall provide services specified in subsection (b)(10) and (11) of this section that are not specifically authorized by the department [~~agency~~].

(4) No person shall provide radiation machine services for a person who cannot produce evidence of a completed application for registration or a valid certificate of registration issued by the department [~~agency~~] except for:

(A) services specified in subsection (b)(11)(B), (C) and (E) of this section; or

(B) the initial installation of the first machine(s) for a new certificate of registration.

(5) The minimum [~~Minimum~~] education and training for persons performing radiation machine assembly, installation, or repair are as follows.

(A) All persons performing radiation machine assembly, installation, or repair shall meet one of the following requirements:

(i) one [~~1~~] year of formal training (may be satisfied by factory school, military technical training school, or other courses in radiation machine assembly, installation or repair techniques) or an associate [~~associate's~~] degree in biomedical equipment repair;

(ii) a bachelor's degree in electrical engineering with specialized training in radiation producing devices; or

(iii) a combination of training and experience totaling one [~~1~~] year to include:

(I) experience or education providing familiarity with the type(s) of equipment to be serviced, to include radiation safety;

(II) knowledge of protective measures to reduce potentially hazardous conditions; and

(III) six [~~6~~] months of supervised assembly and repair of the type(s) of equipment to be serviced.

(B) A registrant holding a valid certificate of registration who has hired individuals to perform services before September 1, 1993, need not comply with the education and training requirements in this paragraph. Individuals hired on or after September 1, 1993, shall comply with the education and training requirements in this paragraph.

(6) Each applicant for providers of equipment shall also submit:

(A) the address of an established main location where the radiation machines, records, etc., will be maintained for inspection. This shall be a street address, not a post office box number; and

(B) a current copy of the applicant's operating and safety procedures [~~which is required when personnel are provided in addition to equipment~~]. This is required when the applicant's personnel are provided to operate the equipment for their client.

(7) Each applicant for department-accepted [~~agency-accepted~~] training courses specifically required by §289.253 of this title (relating to Radiation Safety Requirements for Well Logging Service Operations and Tracer Studies), and §289.255 of this title shall also submit:

(A) a course syllabus;

(B) the number of instructional hours for each subject;

(C) a list of training resources, for example, reference books, texts, workbooks, physical facilities, etc.;

(D) all test questions and corresponding answers; and

(E) the radiation safety training, education, and experience of each instructor.

(8) A record documenting the qualifications of each individual that performs the service shall be made and maintained for inspection by the department per [~~agency in accordance with~~] subsection (v) of this section.

(k) Issuance of certificates of registration.

(1) A certificate of registration application will be approved if the department [~~agency~~] determines that an application meets the requirements of the Act [~~Texas Radiation Control Act (Act)~~] and the requirements of this chapter. The certificate of registration authorizes the proposed activity in the form and contains the conditions and limitations as the department [~~agency~~] deems appropriate or necessary.

(2) The department [~~agency~~] may incorporate in the certificate of registration at the time of issuance, or thereafter by amendment, additional requirements and conditions concerning the registrant's possession, use, and transfer of radiation machines subject to this chapter as it deems appropriate or necessary [~~in order~~] to:

(A) minimize danger to occupational and public health and safety;

(B) require additional reports and the keeping of additional records as may be appropriate or necessary; and

(C) prevent loss or theft of radiation machines subject to this section.

(3) The department [~~agency~~] may request, and the registrant shall provide, additional information after the certificate of registration has been issued to enable the department [~~agency~~] to determine whether the certificate of registration should be modified per [~~in accordance with~~] subsection (s) of this section.

(l) Terms and conditions of certificates of registration.

(1) Each certificate of registration issued per [~~in accordance with~~] this section shall be subject to the applicable provisions of the Act, now or hereafter in effect, and to the applicable rules and orders of the department [~~agency~~].

(2) No certificate of registration issued or granted under this section shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, to any person unless the department [~~agency~~] authorizes the transfer in writing.

(3) Each person registered by the department [~~agency~~] for radiation machine use per [~~in accordance with~~] this section shall confine use and possession of the radiation machine registered to the locations and purposes authorized in the certificate of registration.

(4) In deciding [~~making a determination~~] whether to grant, deny, amend, renew, revoke, suspend, or restrict a certificate of registration, the department [~~agency~~] may consider the technical competence and compliance history of an applicant or holder of a certificate of registration. After an opportunity for a hearing, the department [~~agency~~] shall deny an application for a certificate of registration, an amendment to a certificate of registration, or renewal of a certificate of registration if the applicant's compliance history reveals that at least three department [~~agency~~] actions have been issued against the applicant, within the previous 6 years, that assess administrative or civil penalties against the applicant, or that revoke or suspend the certificate of registration.

(m) Responsibilities of the registrant.

(1) The registrant is responsible for complying with this chapter and the conditions of the certificate of registration.

(2) The registrant shall designate an individual qualified per [~~in accordance with~~] subsection (e)(3) of this section as the radiation safety officer and shall ensure the individual continually performs the responsibilities of the radiation safety officer as identified in subsection (n) of this section.

(3) Persons using radiation machines per [~~in accordance with~~] subsection (f)(1)(B) of this section (concerning radiation accel-

erator or therapeutic radiation machines or electronic brachytherapy devices for human use), subsection (g) of this section (concerning an application for mobile service operations), subsection (i)(1)(A) of this section (concerning persons having an accelerator for non-human use), and subsection (i)(3) of this section (concerning radiation machines in industrial radiographic operations) shall have a valid certificate of registration issued by the department before [~~agency prior to~~] use.

(4) Other than the initial installation of the first machines(s) for a new certificate of registration, no person shall use radiation machines unless they have applied for registration within 30 days of beginning use of the machines per [~~in accordance with~~] subsection (f)(1)(A) of this section.

(5) No registrant shall engage any person for services described in subsection (b)(11) of this section until the person provides to the registrant evidence of registration with the department [~~agency~~].

(6) No person shall provide radiation machine services for a person who cannot produce evidence of a completed application for registration or a valid certificate of registration issued by the department [~~agency~~] except for:

(A) the initial installation of the first machines(s) for a new certificate of registration; and

(B) the registrant authorized for demonstration and sale may demonstrate a radiation machine per [~~in accordance with~~] paragraph (13) of this subsection.

(7) The registrant shall notify the department [~~agency~~] of any changes that would render the information contained in the application for registration or [~~and/or~~] the certificate of registration inaccurate. The notification shall be in writing and signed by an authorized representative.

(A) Notification is required within 30 days after the following changes:

(i) name or mailing address;

(ii) street address where machine will be used;

(iii) additional use location;

(iv) RSO; or

(v) name and registration number of the contracted provider of equipment, registered per [~~in accordance with~~] this section.

(B) The registrant shall notify the department [~~agency~~] within 30 days after [~~of~~] changes in the radiation machines that include:

(i) any change in the category(ies) of machine type or type of use as specified in §289.231(ll) of this title and as authorized in the certificate of registration; or

(ii) any increase in the number of machines authorized by the certificate of registration in any machine type or type of use category.

(8) The registrant, or the parent company, shall notify the department [~~agency~~] in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy. This notification shall include:

(A) the bankruptcy court in which the petition for bankruptcy was filed; and

(B) the case name and number, and date of filing the petition.

(9) The registrant shall inventory all radiation machines in the registrant's possession at an interval not to exceed one [~~1~~] year.

(A) The inventory shall include:

(i) manufacturer's name;

(ii) model and serial number of the control panel; and

(iii) location of radiation machine(s) (for example, room number).

(B) Records of the inventory shall be made and maintained for inspection by the department per [~~agency in accordance with~~] subsection (v) of this section.

(10) The registrant shall maintain records of receipt, transfer, and disposal of radiation machines.

(A) The records shall include:

(i) manufacturer's name;

(ii) model and serial number from the control panel;

(iii) date of the receipt, transfer, and disposal;

(iv) name and address of person machine(s) received from, transferred to, or disposed of; and

(v) name of the individual recording the information.

(B) Records of the receipt, transfer, or disposal of the machine(s) shall be made and maintained for inspection by the department per [~~agency in accordance with~~] subsection (v) of this section.

(11) The persons using loaner radiation machines shall comply with the following.

(A) For persons having a valid certificate of registration, loaner radiation machines may be used for up to 30 days. Within the following 30 days, the registrant shall:

(i) notify the department [~~agency~~] of a change in the category(ies) of machine type or type of use as specified in §289.231(ll) of this title and as authorized in the certificate of registration; or

(ii) notify the department [~~agency~~] of any increase in the number of machines authorized by the certificate of registration in any machine type or type of use category; and

(iii) perform an equipment performance evaluation on the radiation machine(s) per [~~in accordance with~~] §289.227(o) of this title.

(B) For persons who do not hold a valid certificate of registration, loaner radiation machines may be used for human use up to 30 days, by or under the direction of a practitioner, before applying for a certificate of registration per [~~in accordance with~~] subsection (e) of this section. This does not include:

(i) accelerators for human use as described in subsection (f)(1)(B) of this section;

(ii) mobile services as described in subsection (g) of this section;

(iii) healing arts screening as described in subsection (h) of this section;

(iv) accelerators for non-human use as described in subsection (i)(1)(A) of this section; and

(v) industrial radiography as described in subsection (i)(3) of this section.

(12) Persons authorized to provide radiation machines shall comply with the following.

(A) Providers of equipment shall:

(i) ensure that all radiation machines used on humans for healing arts purposes meet the requirements of §289.227(o) of this title; and

(ii) provide radiation machines only to facilities holding a valid certificate of registration.

(B) Providers of equipment shall keep a log of radiation machines provided in Texas. The record shall list the following current information:

(i) date machine is provided;

(ii) name of customer; and

(iii) customer's certificate of registration number.

(C) Records of machines provided shall be made and maintained for inspection by the department per [~~agency in accordance with~~] subsection (v) of this section.

(13) Persons authorized to perform demonstration and sale of radiation machines in Texas shall comply with the following.

(A) A daily log shall be maintained and shall include:

(i) date of all demonstrations and sales of radiation machines performed in Texas;

(ii) name and address of the customer; and

(iii) customer's certificate of registration number unless the service provided is an initial installation as described in paragraph (6) of this subsection.

(B) Records of all demonstrations and sales shall be made and maintained for inspection by the department per [~~agency in accordance with~~] subsection (v) of this section.

(C) Individuals must not be exposed to the useful beam except for healing arts purposes and unless such exposure has been specifically and individually ordered by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:

(i) exposure of an individual for training or demonstration;

(ii) QA/QC testing; or

(iii) other non-healing arts purposes.

[~~(C) Demonstration of radiation machines on humans shall be performed by or under the direction of a practitioner in accordance with paragraph (11) of this subsection.~~]

(D) Demonstration of radiation machines performed by the service provider shall be on phantoms only.

(E) The registrant authorized for demonstration and sale of radiation machines is responsible for performing and documenting all tests required by [~~in accordance with~~] §289.227 of this title when demonstration of a radiation machine involves exposure specifically and individually ordered by a licensed practitioner of the healing arts [~~for radiation machines used on humans for demonstration purposes~~].

(n) Responsibilities of RSOs.

(1) Duties of the RSO include[~~, but are not limited to~~]:

(A) establishing and overseeing operating and safety procedures that maintain radiation exposures as low as reasonably achievable (ALARA)[~~, and to review them at intervals not to exceed 12 months to ensure that the procedures are current and conform with this chapter~~];

(i) review them at intervals not to exceed 12 months to ensure that the procedures are current and conform with this chapter; and

(ii) review and ensure that all actions required in this chapter are performed at the respective intervals to maintain compliance;

(B) ensuring that individual monitoring devices are properly used by occupationally-exposed personnel, [~~that~~] records are kept of the monitoring results, and [~~that~~] timely notifications are made as required by §289.203 of this title;

(C) investigating and reporting to the department [~~agency~~] each known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by this chapter;

(D) assuming control and having the authority to institute corrective actions including the shut-down of operations when necessary in an emergency [~~situations~~] or unsafe conditions; [~~and~~]

(E) ensuring that corrective actions for violations issued by the department are implemented to avoid a repeat violation; and

(F) [~~(E)~~] maintaining records as required by this chapter.

(2) The RSO shall ensure that personnel are adequately trained and complying with this chapter, the conditions of the certificate of registration, and the operating and safety procedures of the registrant.

(3) The RSO shall make entries of the records in paragraph (1) of this subsection at intervals not to exceed 30 days after receipt of a monitoring report.

(o) Responsibilities of assemblers and [~~and/or~~] installers.

(1) No person shall provide radiation machine services for a person who cannot produce evidence of a completed application for registration or a valid certificate of registration issued by the department [~~agency~~] except for the initial installation of the first machine(s) for a new certificate of registration.

(2) Persons who assemble or install radiation machines shall notify the department [~~agency~~] of the following information within 30 days after assembly or [~~of~~] installation:

(A) the name, address, and certificate of registration number, except in the case of initial machine installation, of persons who have received the machines;

(B) the type of radiation machine, the manufacturer's name, model number, and control panel serial number of each radiation machine; and

(C) the date of transfer or disposal of each radiation machine.

(3) Persons who assemble, install, or repair radiation machines, or components of the machines, shall ensure the radiation machines meet the applicable requirement of this chapter when the machines are placed in operation.

(4) Persons assembling, installing, and repairing radiation machines shall keep a daily log to include the following information:

(A) date of service;

(B) name of customer;

(C) customer's certificate of registration number unless the installation is an initial installation described in paragraph (1) of this subsection; and

(D) records of assembling, installing and repairing of the machines shall be made and maintained for inspection by the department per [agency in accordance with] subsection (v) of this section.

(5) Equipment performance evaluations shall be performed as follows:

(A) on all medical, chiropractic or podiatric radiation machines within 30 days after the initial installation, re-installation, and after repair of a machine component that would affect the radiation output that includes but is not limited to the timer, tube, power supply, and thereafter, per [in accordance with] §289.227(o)(1) of this title; and

(B) on all dental radiation machines and radiation machines used in veterinary medicine within 30 days after the initial installation, re-installation, and after repair of a machine component that would affect the radiation output that includes [but is not limited to] the timer, tube, and power supply, and thereafter, per §289.232(j)(5)(J)(i) [in accordance with §289.232(i)(7)] and §289.233(j)(5)(N)(i)(I) - (III) [§289.232(i)(5)(N)] of this title, as applicable.

(6) Radiation air kerma rate [exposure rate (air kerma rate)] or dose measurements for fluoroscopy and computed tomography (CT) radiation machines, as required by §289.227 and §289.233 of this title shall be performed by a licensed medical physicist with a specialty in diagnostic medical physics.

(7) Radiation entrance exposure [(air kerma)] data required during EPEs on general radiographic and special purpose radiation machines, as defined in §289.227(e) and §289.233(d) of this title, shall be performed by or under the supervision of a licensed medical physicist with a specialty in diagnostic medical physics. The physicist shall:

(A) establish written procedures for non-physicists that document entrance exposure [(air kerma)] data;

(B) calculate the entrance exposure [(air kerma)];

(C) verify the entrance exposure [(air kerma)] meets compliance with §289.227(j) of this title;

(D) retest the machine, by measuring entrance exposure, at the facility's specified technique after repair or adjustment by a service technician; [sign the EPE reports.]

(E) submit any test or EPE results to the facility within 30 days after completion of testing. Documentation shall include:

(i) name of the facility;

(ii) address of facility; if satellite facility, address of where the radiation machine is located;

(iii) business email address;

(iv) registration number of the facility;

(v) make, model, and serial number from the machine control panel;

(vi) registration number of physicist and service company performing EPE;

(vii) mailing/business address of physicist performing EPE;

(viii) date of the last calibration of testing equipment;

(ix) signature of physicist that performed the EPE;

(F) retain documentation of subparagraph (E) of this paragraph according to subsection (v) of this section; and

(G) maintain a calibrated dosimetry system available for use:

(i) The system shall be calibrated by the National Institute for Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL).

(ii) The calibration shall be performed within the previous 24 months and after any servicing that may have affected system calibration.

(p) Expiration of certificates of registration.

(1) Except as provided by subsection (r) of this section, each certificate of registration expires at the end of the day, in the month and year stated in the certificate of registration.

(2) If a registrant does not submit an application for renewal of the certificate of registration per [in accordance with] subsection (r) of this section, as applicable, on or before the expiration date specified in the certificate of registration, the registrant shall:

(A) terminate use of all radiation machines and [and/or] terminate radiation machine servicing or radiation services as applicable; and

(B) pay any outstanding fees per [in accordance with] §289.204 of this title.

(3) The expiration [Expiration] of the certificate of registration does not relieve the registrant of the requirements of this chapter.

(q) Termination of certificates of registration.

(1) When a registrant decides to terminate all activities involving radiation machines or services authorized under the certificate of registration, the registrant shall immediately:

(A) request termination of the certificate of registration in writing signed by the RSO, owner, or an individual authorized to act on behalf of the registrant; and

(B) submit to the department [agency] a record of the disposition of the radiation machines, if applicable; and if transferred, to whom they are transferred.

(2) The registrant shall pay any outstanding fees per [in accordance with] §289.204 of this title.

(r) Renewal of certificates of registration.

(1) An application for renewal of a certificate of registration shall be filed per [in accordance with] subsection (e) of this section and applicable paragraphs of subsections (f) - (j) of this section.

(2) If a registrant applies [files an application] for [a] renewal in proper form before the existing certificate of registration expires, such [existing] certificate of registration shall not expire until the application status has been determined by the department [agency].

(s) Modification, suspension, and revocation of certificates of registration.

(1) The terms and conditions of all certificates of registration shall be subject to revision or modification. A certificate of registration may be suspended or revoked because [by reason] of amend-

ments to the Act, because of amendments to the [~~by reason of~~] rules in this chapter, or orders issued by the department [~~agency~~].

(2) Any certificate of registration may be revoked, suspended, or modified, in whole or in part, for:

(A) any material false statement in the application or any statement of fact required under provisions of the Act;

(B) conditions revealed by such application or statement of fact or any report, record, or inspection, or other means that would warrant the department [~~agency~~] to refuse to grant a certificate of registration on an original application;

(C) violation of, or failure to observe any of the terms and conditions of the Act, this chapter, the certificate of registration, or order of the department [~~agency~~]; or

(D) existing conditions that constitute a substantial threat to [~~the~~] public health or safety or the environment.

(3) Each certificate of registration revoked by the department [~~agency~~] ends at the end of the day on the date of the department's [~~agency's~~] final determination to revoke the certificate of registration, or on the revocation date stated in the determination, or as otherwise provided by the department [~~agency~~] order.

(4) Except in cases in which the occupational and public health or safety requires otherwise, no certificate of registration shall be suspended or revoked unless, before [~~prior to~~] the institution of proceedings, therefore, facts or conduct that may warrant such action shall have been called to the attention of the registrant in writing and the registrant shall have been allowed [~~afforded an opportunity~~] to demonstrate compliance with all lawful requirements.

(t) Reciprocal recognition of out-of-state certificates of registration.

(1) Whenever any radiation machine is to be brought into the state for any temporary use, the person proposing to bring the machine into the state shall apply for and receive a notice from the department [~~agency~~] granting reciprocal recognition before [~~prior to~~] beginning operations. The request for reciprocity shall include a:

(A) completed RC Form 226-1 (Business Information Form);

(B) completed RC Form 226-3 (Application for Registration of Industrial Radiation Machines);

(C) RSO qualifications per subsection (e)(3) of this section.

(D) [~~(C)~~] completed RC [~~BRC~~] Form 252-3 (Notice of Intent to Work in Texas Under Reciprocity);

(E) [~~(D)~~] completed qualification forms (RC [~~BRC~~] Forms 255-E, 255-T or [~~and/or~~] 255-OS) for each radiographer who will be working in Texas if the reciprocity request is for industrial radiography;

[~~(E) name and Texas licensing board number of the practitioner if the radiation machines are used on humans;~~]

(F) copy of the applicant's current certificate of registration or equivalent document;

(G) copy of the applicant's current operating and safety procedures pertinent to the proposed use; and

(H) the fee as specified in §289.204(d) of this title. [~~; and~~]

[~~(I) qualifications of personnel who will be operating the machines for human use.~~]

(2) Upon a determination that the request for reciprocity meets the requirements of the department [~~agency~~], the department [~~agency~~] may issue a notice granting reciprocal recognition authorizing the proposed use.

(3) Once reciprocity is granted, the out-of-state registrant shall file a RC [~~BRC~~] Form 252-3 with the department before [~~agency prior to~~] each entry into the state. This form shall be filed at least three [~~3~~] working days before the radiation machine is to be used in the state. If, for a specific case, the three-day [~~3-day~~] period would impose an undue hardship, the out-of-state registrant may, at the determination of the department [~~agency~~], obtain permission to proceed sooner.

(4) When radiation machines are used as authorized under reciprocity, the out-of-state registrant shall have the following in its possession at all times for inspection by the department [~~agency~~]:

(A) completed RC [~~BRC~~] Form 252-3;

(B) copy of the notice from the department [~~agency~~] granting reciprocity;

(C) copy of the out-of-state registrants operating and safety procedures; and

(D) copy of the applicable rules as specified in the notice granting reciprocity.

(5) If the state from which the radiation machine is proposed to be brought does not issue certificates of registration or equivalent documents, a certificate of registration shall be obtained from the department per [~~agency in accordance with~~] the requirements of this section.

(6) The department [~~agency~~] may withdraw, limit, or qualify its acceptance of any certificate of registration or equivalent document issued by another department [~~agency~~] upon determining that the action is necessary [~~in order~~] to prevent an undue hazard to occupational and public health and safety or property.

(7) Reciprocal recognition will expire two [~~2~~] years from the date it is granted. A new request for reciprocity shall be submitted to the department [~~agency~~] every two [~~2~~] years. Reciprocity requests made after the initial request shall include the following:

(A) completed RC Form 226-1(Business Information Form);

(B) completed RC Form 226-3 (Application for Registration of Industrial Radiation Machines);

(C) RSO qualifications in accordance with subsection (e)(3) of this section.

(D) [~~(C)~~] completed RC [~~BRC~~] Form 252-3 (Notice of Intent to Work in Texas Under Reciprocity);

(E) [~~(D)~~] completed qualification forms RC [~~(BRC~~] Forms 255-E, 255-T or [~~and/or~~] 255-OS for each radiographer who will be working in Texas if the reciprocity request is for industrial radiography;

[~~(E) name and Texas licensing board number of the practitioner if the radiation machines are used on humans;~~]

(F) copy of the applicant's current certificate of registration or equivalent document;

(G) copy of the applicant's current operating and safety procedures pertinent to the proposed use; and

(H) the fee as specified in §289.204(d) of this title. [; and]

[(I) qualifications of personnel who will be operating the machines.]

(8) Radiation services provided by a person from out-of-state will not be granted reciprocity. Whenever radiation services are to be provided by a person from out-of-state, that person shall apply for and receive a certificate of registration from the department [agency] before providing radiation services. The application shall be filed per [in accordance with] subsections (e), (i), and (j) of this section, as applicable.

(u) Medical research and investigational devices.

(1) Any research using radiation machines on humans shall be approved by an Investigational Review Board (IRB) as required by Title 45, Code of Federal Regulations (CFR), Part 46 and Title 21, CFR, Part 56. The IRB shall include at least one physician to direct any use of radiation per [in accordance with] §289.231(b) of this title.

(2) Facilities with radiation machines with investigational device exemptions that are involved in clinical studies shall comply with primary regulations that govern the conduct of clinical studies and that apply to the manufacturers, sponsors, clinical investigators, institutional review boards, and the medical device. These regulations include:

(A) 21 CFR, Part 812, Investigational Device Exemptions;

(B) 21 CFR, Part 50, Protection of Human Subjects;

(C) 21 CFR, Part 56, Institutional Review Boards;

(D) 21 CFR, Part 54, Financial Disclosure by Clinical Investigators; and

(E) 21 CFR, Part 820 [821], Subpart C, Design Controls of the Quality System Regulation.

(v) Record/document retention requirements for registration of radiation machines.

(1) Each registrant shall maintain the following records/documents at each site, including authorized records sites for mobile services, at the time intervals specified for inspection by the department [agency].

Figure: 25 TAC §289.226(v)(1)

[Figure: 25 TAC §289.226(v)(1)]

(2) Records listed in paragraph (1) of this subsection may be maintained in electronic format.

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

Filed with the Office of the Secretary of State on March 19, 2021.

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Barbara L. Klein
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Department of State Health Services
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