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 10. COMMUNITY DEVELOPMENT

PART 1. TEXAS DEPARTMENT OF HOUSING AND COMMUNITY AFFAIRS

CHAPTER 7. HOMELESSNESS PROGRAMS SUBCHAPTER C. EMERGENCY SOLUTIONS GRANTS (ESG)

10 TAC §7.34, §7.36

The Texas Department of Housing and Community Affairs (the Department) proposes the repeal of 10 TAC Chapter 7, Subchapter C, Emergency Solutions Grants (ESG), §7.34 Continuing Awards and §7.36 General Threshold Criteria. The purpose of the repeals is to eliminate an outdated rule, while adopting a new updated rule under separate action.

The Department has analyzed this proposed rulemaking and the analysis is described below for each category of analysis performed.

a. GOVERNMENT GROWTH IMPACT STATEMENT REQUIRED BY TEX. GOV'T CODE §2001.0221.

1. Mr. Bobby Wilkinson, Executive Director, has determined that, for the first five years the proposed repeal would be in effect, the proposed repeal does not create or eliminate a government program, but relates to the repeal, and simultaneous readoption making changes to an existing activity, administration of the Department's Emergency Solutions Grants (ESG) Program.

2. The proposed repeal does not require a change in work that would require the creation of new employee positions, nor is the proposed repeal significant enough to reduce workload to a degree that any existing employee positions are eliminated.

3. The proposed repeal does not require additional future legislative appropriations.

4. The proposed repeal does not result in an increase in fees paid to the Department, nor a decrease in fees paid to the Department.

5. The proposed repeal is not creating a new regulation, except that it is being replaced by a new rule simultaneously to provide for revisions.

6. The proposed action will repeal an existing regulation, but is associated with a simultaneous readoption making changes to an existing activity, the administration of the Department's Emergency Solutions Grant Program.

7. The proposed repeal will not increase or decrease the number of individuals subject to the rule's applicability.

8. The proposed repeal will not negatively or positively affect the state's economy.

b. ADVERSE ECONOMIC IMPACT ON SMALL OR MICRO-BUSINESSES OR RURAL COMMUNITIES AND REGULATORY FLEXIBILITY REQUIRED BY TEX. GOV'T CODE §2006.002.

The Department has evaluated this proposed repeal and determined that the proposed repeal will not create an economic effect on small or micro-businesses or rural communities.

c. TAKINGS IMPACT ASSESSMENT REQUIRED BY TEX. GOV'T CODE §2007.043. The proposed repeal does not contemplate or authorize a taking by the Department; therefore, no Takings Impact Assessment is required.

d. LOCAL EMPLOYMENT IMPACT STATEMENTS REQUIRED BY TEX. GOV'T CODE §2001.024(a)(6).

The Department has evaluated the proposed repeal as to its possible effects on local economies and has determined that for the first five years the proposed repeal would be in effect there would be no economic effect on local employment; therefore, no local employment impact statement is required to be prepared for the rule.

e. PUBLIC BENEFIT/COST NOTE REQUIRED BY TEX. GOV'T CODE §2001.024(a)(5). Mr. Wilkinson has determined that, for each year of the first five years the proposed repeal is in effect, the public benefit anticipated as a result of the repealed sections would be updated and more germane rules. There will not be economic costs to individuals required to comply with the repealed sections.

f. FISCAL NOTE REQUIRED BY TEX. GOV'T CODE §2001.024(a)(4). Mr. Wilkinson also has determined that for each year of the first five years the proposed repeal is in effect, enforcing or administering the repeal does not have any foreseeable implications related to costs or revenues of the state or local governments.

REQUEST FOR PUBLIC COMMENT. The public comment period will be held February 21, 2025, to March 21, 2025, to receive input on the proposed repealed sections. Written comments may be submitted to the Texas Department of Housing and Community Affairs, Attn: Rosy Falcon, Rule Comments, P.O. Box 13941, Austin, Texas 78711-3941 or email rosy.falcon@tdhca.texas.gov. ALL COMMENTS MUST BE RECEIVED BY 5:00 p.m., Central Time, March 21, 2025.

STATUTORY AUTHORITY. The proposed repeal is made pursuant to Tex. Gov't Code §2306.053, which authorizes the Department to adopt rules.

Except as described herein the proposed repealed sections affect no other code, article, or statute.

§7.34. Continuing Awards.

§7.36. General Threshold Criteria.

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 February 6, 2025.

TRD-202500415
Bobby Wilkinson
Executive Director
Texas Department of Housing and Community Affairs
Earliest possible date of adoption: March 23, 2025
For further information, please call: (512) 475-3959

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10 TAC §7.34, §7.36

The Texas Department of Housing and Community Affairs (the Department) proposes new Chapter 7, Subchapter C, Emergency Solutions Grants (ESG), §7.34 Continuing Awards and §7.36 General Threshold Criteria. The purpose of the proposed new sections is to take steps to better incentivize compliance with HUD's annual reporting requirements.

Tex. Gov't Code §2001.0045(b) does not apply to the rule proposed for action because it was determined that no costs are associated with this action, and therefore no costs warrant being offset.

The Department has analyzed this proposed rulemaking and the analysis is described below for each category of analysis performed.

a. GOVERNMENT GROWTH IMPACT STATEMENT REQUIRED BY TEX. GOV'T CODE §2001.0221.

Mr. Bobby Wilkinson, Executive Director, has determined that, for the first five years the proposed new rule would be in effect:

1. The proposed sections do not create or eliminate a government program, but relate to the readoption of this rule which makes changes to administration of the Department's Emergency Solutions Grants Program.

2. The proposed new sections do not require a change in work that would require the creation of new employee positions, nor are the rule changes significant enough to reduce work load to a degree that eliminates any existing employee positions.

3. The proposed new sections do not require additional future legislative appropriations.

4. The proposed new sections will not result in an increase in fees paid to the Department nor a decrease in fees paid to the Department.

5. The proposed new sections are not creating a new regulation, except that it is replacing a rule being repealed simultaneously to provide for revisions.

6. The proposed new sections will not expand or repeal an existing regulation.

7. The proposed new sections will not increase or decrease the number of individuals subject to the rule's applicability.

8. The proposed new sections will not negatively or positively affect the state's economy.

b. ADVERSE ECONOMIC IMPACT ON SMALL OR MICRO-BUSINESSES OR RURAL COMMUNITIES AND REGULATORY FLEXIBILITY REQUIRED BY TEX. GOV'T CODE §2006.002. The Department, in drafting these proposed new sections, has attempted to reduce any adverse economic effect on small or micro-business or rural communities while remaining consistent with the statutory requirements of Tex. Gov't Code §2306.111.

1. The Department has evaluated these proposed new sections and determined that none of the adverse effect strategies outlined in Tex. Gov't Code §2006.002(b) are applicable.

2. The Department has determined that because the proposed new sections serve to clarify and update existing requirements and do not establish new requirements for which there would be an associated cost, there will be no economic effect on small or micro-businesses or rural communities.

c. TAKINGS IMPACT ASSESSMENT REQUIRED BY TEX. GOV'T CODE §2007.043. The proposed new sections do not contemplate or authorize a taking by the Department; therefore, no Takings Impact Assessment is required.

d. LOCAL EMPLOYMENT IMPACT STATEMENTS REQUIRED BY TEX. GOV'T CODE §2001.024(a)(6).

The Department has evaluated the proposed new sections as to their possible effects on local economies and has determined that for the first five years the rule will be in effect the proposed new sections have no economic effect on local employment because the rule serves to clarify and update existing requirements and does not establish new requirements or activities that may positively or negatively impact local economies.

Tex. Gov't Code §2001.022(a) states that this "impact statement must describe in detail the probable effect of the rule on employment in each geographic region affected by this rule" Considering that participation in the Department's Homeless Programs is at the discretion of the local government or other eligible subrecipients, there are no "probable" effects of the proposed new sections on particular geographic regions.

e. PUBLIC BENEFIT/COST NOTE REQUIRED BY TEX. GOV'T CODE §2001.024(a)(5). Bobby Wilkinson, Executive Director, has determined that, for each year of the first five years the proposed new sections are in effect, the public benefit anticipated as a result of the rule will be a more germane rule that better aligns administration to federal and state requirements. There will not be any economic cost to any individuals required to comply with the new sections because the processes described by the rule have already been in place through the rule found at this section being repealed.

f. FISCAL NOTE REQUIRED BY TEX. GOV'T CODE §2001.024(a)(4). Mr. Wilkinson also has determined that for each year of the first five years the proposed new sections are in effect, enforcing or administering the rule does not have any foreseeable implications related to costs or revenues of the state or local governments because the rule updates and clarifies existing requirements and does not impose new requirements.

REQUEST FOR PUBLIC COMMENT. The public comment period will be held February 21, 2025, to March 21, 2025, to receive input on the proposed new sections. Written comments may be submitted to the Texas Department of Housing and Community Affairs, Attn: Rosy Falcon, Rule Comments, P.O. Box 13941, Austin, Texas 78711-3941 or email rosy.falcon@td-

hca.texas.gov. ALL COMMENTS MUST BE RECEIVED BY 5:00 p.m., Central Time, March 21, 2025.

STATUTORY AUTHORITY. The new sections are proposed pursuant to Tex. Gov't Code §2306.053, which authorizes the Department to adopt rules.

Except as described herein the proposed new sections affect no other code, article, or statute.

§7.34. Continuing Awards.

(a) TDHCA will withhold a portion of funds from the competition for funds to be used for continuing awards to prior Subrecipients of its ESG allocation, not including ESG CARES or Contracts for reallocated funds from prior years only, in accordance with §7.33 of this subchapter (related to Apportionment of ESG Funds).

(b) ESG funds withheld for continuing awards by the Department will be allocated in accordance with the Allocation Formula, and are not subject to the award process and requirements outlined in §7.38 of this subchapter (relating to Competitive Award and Funding Process).

(c) The subsequent years of allocation of ESG funds received by the Department will be offered to eligible Subrecipients of ESG funds (not including ESG CARES) that were awarded funds from at least three of the prior four allocations of ESG. An ESG Subrecipient is eligible for an offer of a continuing award of funds if the Subrecipient meets the following requirements:

(1) Submits an abbreviated Application for funding within 21 days of the request from the Department as promulgated by the Department;

(2) Resolves administrative deficiencies within the timeframe and in the manner outlined in §7.37 of this subchapter (relating to Application Review and Administrative Deficiency Process for Department NOFAs);

(3) Submitted two or fewer delinquent monthly reports for each of their active ESG Contracts or for the most recently closed ESG Contract if there are no active ESG Contracts, (not including ESG CARES) for reports due in the six-month period preceding the application submission deadline;

(4) Satisfies the requirements of the Previous Participation Review as provided for in §1.302 of this title (relating to Previous Participation Reviews for Department Program Awards Not Covered by §1.301 of this title);

(5) Does not have unresolved monitoring findings in any TDHCA funded program after the corrective action period;

(6) Does not have monitoring findings in any TDHCA funded program which resulted in disallowed costs in excess of $5,000;

(7) Does not apply for funds within the same COC Region under the competitive Application process for Program Participant service(s) in which they are already funded for a Continuing Award;

(8) Expended a minimum of 95% of their contracted award amount, as amended in their most recently closed ESG Contract (not including ESG CARES);

(9) Did not voluntarily deobligate an amount that exceeds 5% of their contracted award amount, as amended for increases due to reallocated funds, on their most recently closed ESG Contract (not including ESG CARES);

(10) Submitted the most recent yearly report information, as required in 10 TAC §7.5(h)(1), in SAGE by the deadline established by the Department for the report due in the period preceding the application submission deadline; and

(11) Is approved by the Department's Governing Board.

(d) Any offer of ESG funds made under this section is contingent on retaining similar terms and conditions or agreeing to adjustments reflective of funding amount, including but not limited to performance and match requirements, in the active ESG annual Contract issued under a NOFA.

(e) Offers of funding will be based on the prior year's award, excluding Contracts comprised exclusively of reallocated funds, before amendments, and will be proportionally increased or decreased in proportion to the total amount of ESG funds available subject to the allocation formula.

(f) If additional funds are made available due to reduced continuing awards in the region, awards may be increased proportionate to the increased withheld funds. In any event, an increased award from funds made available from reduced awards may not exceed 115% of the award amount under the allocation or the maximum award amount established in the NOFA.

(g) Funds that remain available after all eligible continuing awards have been accepted will be transferred to the competition for funds for the regional competition in accordance with §7.38 of this subchapter.

(h) Percentages identified in this section will not be rounded up to the nearest whole number.

§7.36. General Threshold Criteria.

(a) Applications submitted to the Department are subject to general threshold criteria. Applications which do not meet the general threshold criteria or which cannot resolve an administrative deficiency related to general threshold criteria are subject to termination. Applicants applying directly to the Department to administer the ESG Program must submit an Application on or before the deadlines specified in the NOFA, notification of a direct Subgrant, or notification of availability of a continuing award, and must include items in paragraphs (1) - (13) of this subsection:

(1) Application materials as published by the Department including, but not limited to, program description, budget, and performance statement.

(2) An ESG budget that does not exceed the total amount available within the CoC region, other geographic limitation, Subgrant, or offer of continuing award, as applicable.

(3) A copy of the Applicant's written standards that comply with the requirements of 24 CFR §576.400 and certification of compliance with these standards. Any occupancy standard set by the Subrecipient must not conflict with local regulations or Texas Property Code §92.010.

(4) A copy of the Applicant's policy for termination of assistance that complies with the requirements of 24 CFR §576.402 and certification of compliance with these standards.

(5) A Service Area which consists of at least the entirety of one county or multiple counties within the CoC region under which Application is made, unless a CoC region does not include an entire county. When the CoC region does not encompass at least the entirety of one county, the Service Area must encompass the entire CoC region. The Service Area selected within an Application must be fully contained within one CoC region.

(6) Commitment in the budget to the provision of 100% Match, or request for a Match waiver, as applicable. Match waivers

will be considered by the Department based on the rank of the Application. Applicants requesting an award of funds in excess of the minimum award amount as described in the NOFA for Program Participant services are not eligible to request or receive a Match waiver. In the event that the Match waivers requested exceed $100,000, the waivers will be considered only for the highest scoring eligible Applications, subject to availability of excess Match provided by ESG Applicants. Applicants that do not receive the waiver and are unable to provide a source of Match will be ineligible for an ESG award.

(7) Applicant certification of compliance with State and federal laws, rules and guidance governing the ESG Program as provided in the Application.

(8) Evidence of a Unique Entity Identifier (UEI) number for Applicant.

(9) Documentation of existing Section 501(c) tax-exempt status, as applicable.

(10) Completed previous participation review materials, as outlined in Chapter 1, Subchapter C of this title (relating to Previous Participation), for Applicant.

(11) Local government approval per 24 CFR §576.202(a)(2) for an Applicant that will be providing shelter activities with ESG or as ESG Match, as applicable. This documentation must be submitted not later than 30 calendar days after the Application submission deadline as specified in the NOFA, or prior to execution of a Contract for Subrecipients subject to a direct Subgrant, or continuing award. Receipt of the local government approval is a condition prior to the Department obligating ESG funding.

(12) A resolution or other governing body action from the Applicant's direct governing body which includes:

(A) Authorization of the submission of the Application;

(B) Title of the person authorized to represent the entity and who also has signature authority to execute a Contract; and

(C) Date that the resolution was passed by the governing body, which must be not older than 12 months preceding the date the Application is submitted.

(13) Applicants with an ESG Contract(s) must have submitted the most recent yearly report information, as required in 10 TAC §7.5(h)(1), in SAGE by the deadline established by the Department for the report due in the period preceding the application submission deadline.

(b) An Application must be substantially complete when received by the Department. An Application may be terminated if the Application is so unclear or incomplete that a thorough review cannot reasonably be performed, as determined by the Department. Such Application will be terminated without being processed as an administrative deficiency. Specific reasons for a Department termination will be included in the notification sent to the Applicant but, because the termination may occur prior to completion of the full review, will not necessarily include a comprehensive list of all deficiencies in the Application. Termination of an Application may be subject to §1.7 of this title (relating to Appeals Process).

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 February 6, 2025.

TRD-202500416
Bobby Wilkinson
Executive Director
Texas Department of Housing and Community Affairs
Earliest possible date of adoption: March 23, 2025
For further information, please call: (512) 475-3959

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TITLE 25. HEALTH SERVICES

PART 1. DEPARTMENT OF STATE HEALTH SERVICES

CHAPTER 27. CASE MANAGEMENT FOR CHILDREN AND PREGNANT WOMEN

The Executive Commissioner of the Texas Health and Human Services Commission (HHSC) proposes the repeal of §27.1, Purpose and Application; §27.3, Definitions; §27.5, Client Eligibility; §27.7, Client Rights; §27.9, Client Confidentiality; §27.11, Components of Case Management for Children and Pregnant Women Services; §27.13, Prior Authorization; §27.15, Provider Qualifications; §27.17, Provider Approval Process; §27.19, Provider Responsibilities; §27.21, Case Manager Qualifications; §27.23, Case Manager Responsibilities; §27.25, Utilization and Quality Assurance Reviews and Compliance; and §27.27, Termination, Suspension, Probation, and Reprimand of Providers.

BACKGROUND AND PURPOSE

Case Management for Children and Pregnant Women (CPW) services assist eligible Medicaid clients in gaining access to necessary medical, social, educational, and other services related to the client's health conditions and health risks. To be eligible for services, a client must be either a child with a health condition or health risk or a pregnant woman with a high-risk condition. The client must also be Medicaid-eligible in Texas, need case management for CPW services, and choose such services.

HHSC proposes to repeal Chapter 27, Case Management for Children and Pregnant Women, in Title 25, Part 1, Texas Administrative Code (TAC), and proposes a new Chapter 257, Case Management for Children and Pregnant Women, in Title 26, Part 1, TAC. The purpose for moving the CPW chapter from Title 25 to Title 26 is to conform administrative rules to current HHSC practices based on Senate Bill (S.B.) 200, 84th Legislature, Regular Session, 2015. S.B. 200 consolidated functions in the Texas Health and Human Services delivery system and transferred programs, to include CPW, from the Department of State Health Services (DSHS) to HHSC.

The new CPW rules in 26 TAC Chapter 257 are proposed elsewhere in this issue of *Texas Register*.

SECTION-BY-SECTION SUMMARY

The proposed repeal of §§27.1, 27.3, 27.5, 27.7, 27.9, 27.11, 27.13, 27.15, 27.17; 27.19, 27.21, 27.23, 27.25, and 27.27 in 25 TAC Chapter 27 removes rules that need to be replaced by new rules in Title 26 under HHSC.

FISCAL NOTE

Trey Wood, HHSC Chief Financial Officer, has determined that for each year of the first five years that the repeals will be in effect, enforcing or administering the repeals does not have fore-

seeable implications relating to costs or revenues of state or local governments.

GOVERNMENT GROWTH IMPACT STATEMENT

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

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

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

(3) implementation of the proposed repeals will result in no assumed change in future legislative appropriations;

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

(5) the proposed repeals will not create a new regulation;

(6) the proposed repeals will repeal existing regulations;

(7) the proposed repeals will not change the number of individuals subject to the repeals; and

(8) the proposed repeals 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 to comply with the proposed repeals because provider and client participation in CPW is optional.

LOCAL EMPLOYMENT IMPACT

The proposed repeals will not affect a local economy.

COSTS TO REGULATED PERSONS

Texas Government Code §2001.0045 does not apply to these repeals because the repeals do not impose a cost on regulated persons and are necessary to implement legislation that does not specifically state that §2001.0045 applies to the repeals.

PUBLIC BENEFIT AND COSTS

Emily Zalkovsky, State Medicaid Director, has determined that for each year of the first five years the repeals are in effect, the public will benefit from having all HHSC rules in the same title of the TAC.

Trey Wood has also determined that for the first five years the repeals are in effect, there are no anticipated economic costs to persons who are required to comply with the proposed repeals because the existing benefits will be reintroduced in the new rules.

TAKINGS IMPACT ASSESSMENT

HHSC has determined that the proposal does not restrict or limit an owner's right to the owner's 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 4601 West Guadalupe Street, 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 faxing or emailing comments, please indicate "Comments on Proposed Rule 24R049" in the subject line.

SUBCHAPTER A. GENERAL PROVISIONS

25 TAC §27.1, §27.3

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 operation and provision of services by the health and human services agencies, and Texas Government Code §531.033, which authorizes the Executive Commissioner of HHSC to adopt rules as necessary to carry out the commission's duties; and Human Resources Code §32.021 and Texas Government Code §531.021(a), which authorize HHSC to administer the federal medical assistance (Medicaid) program.

The repeals affect Texas Government Code §531.651, §531.652, §531.653, §531.654, §531.655, and §531.656.

§27.1. Purpose and Application.

§27.3. 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 February 5, 2025.

TRD-202500394
Karen Ray
Chief Counsel
Department of State Health Services
Earliest possible date of adoption: March 23, 2025
For further information, please call: (512) 438-2910

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SUBCHAPTER B. CLIENT SERVICES

25 TAC §§27.5, 27.7, 27.9, 27.11, 27.13

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 operation and provision of services by the health and human services agencies, and Texas Government Code §531.033, which authorizes the Executive Commissioner of HHSC to adopt rules as necessary to carry out the commission's duties; and Human Resources Code §32.021 and Texas Government Code §531.021(a), which authorize HHSC to administer the federal medical assistance (Medicaid) program.

The repeals affect Texas Government Code §531.651, §531.652, §531.653, §531.654, §531.655, and §531.656.

§27.5. Client Eligibility.
§27.7. Client Rights.
§27.9. Client Confidentiality.
§27.11. Components of Case Management for Children and Pregnant Women Services.
§27.13. Prior Authorization.

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 February 5, 2025.

TRD-202500395
Karen Ray
Chief Counsel
Department of State Health Services
Earliest possible date of adoption: March 23, 2025
For further information, please call: (512) 438-2910

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SUBCHAPTER C. PROVIDER QUALIFICATIONS AND RESPONSIBILITIES

25 TAC §§27.15, 27.17, 27.19, 27.21, 27.23, 27.25, 27.27

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 operation and provision of services by the health and human services agencies, and Texas Government Code §531.033, which authorizes the Executive Commissioner of HHSC to adopt rules as necessary to carry out the commission's duties; and Human Resources Code §32.021 and Texas Government Code §531.021(a), which authorize HHSC to administer the federal medical assistance (Medicaid) program.

The repeals affect Texas Government Code §531.651, §531.652, §531.653, §531.654, §531.655, and §531.656.

§27.15. Provider Qualifications.
§27.17. Provider Approval Process.
§27.19. Provider Responsibilities.
§27.21. Case Manager Qualifications.
§27.23. Case Manager Responsibilities.
§27.25. Utilization and Quality Assurance Reviews and Compliance.
§27.27. Termination, Suspension, Probation, and Reprimand of Providers.

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 February 5, 2025.

TRD-202500396
Karen Ray
Chief Counsel
Department of State Health Services
Earliest possible date of adoption: March 23, 2025
For further information, please call: (512) 438-2910

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CHAPTER 289. RADIATION CONTROL
SUBCHAPTER E. REGISTRATION REGULATIONS

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 §289.230, concerning Certification of Mammography Systems and Mammography Machines Used for Interventional Breast Radiography, and the repeal of §289.234, concerning Mammography Accreditation.

BACKGROUND AND PURPOSE

The purpose of the proposal is to amend §289.230, relating to requirements for the certification and use of radiation machines in mammography and interventional breast radiography. The amendment is necessary to align with the United States Food and Drug Administration (FDA) Mammography Quality Standards Act (MQSA) under 21 Code of Federal Regulations (CFR) Part 900.

Additionally, the proposal repeals §289.234, relating to mammography accreditation, because DSHS no longer accredits mammography facilities due to an expired contract which ended on August 31, 2024. With the contract's expiration, this rule is no longer valid.

SECTION-BY-SECTION SUMMARY

The proposed amendment to §289.230 updates the requirements concerning breast tissue density in mammography reports and plain language notification statements to patients. Three new outcome data reporting requirements for the interpreting physician and the facility have been added. The outcome data report must include calculations for positive predictive value, cancer detection rate, and recall rate.

Additional changes to §289.230 include reorganizing the rule to mirror the layout of other sections of this chapter, adding survey report requirements, and adding and clarifying definitions for various terms related to mammography machines. The proposal adopts 21 CFR Part 900 by reference for system design, screen-film, processor performance testing, equipment variances, and investigational device requirements. The proposed changes enhance clarity, safety, and regulatory compliance in the field of mammography. Other edits are made to improve grammar, formatting, and rule clarity.

The proposed repeal of §289.234 is necessary to delete an invalid rule.

FISCAL NOTE

Christy Havel Burton, DSHS 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 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 rules will be in effect:

(1) the proposed rules will 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 not create a new regulation;

(6) the proposed rules will expand and repeal existing regulations;

(7) the proposed rules will decrease the number of individuals subject to the rules; and

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

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

Christy Havel Burton has also determined that there will be an adverse economic effect on small businesses or micro-businesses, or rural communities because there may be a cost to comply with new data reporting requirements.

DSHS estimates that the number of mammography facilities subject to the proposal for §289.230 is 668. The projected economic impact cannot be determined because the impact is based on the size of the facility and the age of its current software.

DSHS determined that alternative methods to achieve the purpose of the proposed rules for small businesses, micro-businesses, or rural communities would not be consistent with ensuring the health and safety of the public, employees, and patients.

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 comply with federal law: 21 CFR Part 900, and to protect the health, safety, and welfare of the residents of Texas.

PUBLIC BENEFIT AND COSTS

Dr. Timothy Stevenson, Deputy Commissioner, Consumer Protection Division, has determined that for each year of the first five years the rules are in effect, the anticipated public benefit will be improved protection from unnecessary exposure to radiation for the public, patients, workers, and the environment.

Christy Havel Burton has also determined that for the first five years the rules are in effect, persons required to comply with the proposed rules may incur economic costs because new outcome data reporting requirements may require additional software or increase staff workload. The proposed rules do not increase registration fees or increase the frequency of fee payment.

TAKINGS IMPACT ASSESSMENT

DSHS has determined that the proposal does not restrict or limit an owner's right to the owner's 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 4601 West Guadalupe Street, 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) faxed or 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 faxing or emailing comments, please indicate "Comments on Proposed Rule 24R087" in the subject line.

25 TAC §289.230

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 regulations; §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 relating to inspection of x-ray equipment; Chapter 401, Subchapter J, which authorizes enforcement of the Act; Chapter 401, Subchapter L, which provides for the Certification of Mammography Systems; and Texas Government Code §531.0055 and Texas Health and Safety Code §1001.075, which authorize the Executive Commissioner of HHSC to adopt rules and policies for the operation and provision of health and human services by DSHS and the administration of Texas Health and Safety Code Chapter 1001.

§289.230. Certification of Mammography Systems and X-Ray [~~Mammography~~] Machines Used for Interventional Breast Radiography.

(a) Purpose. This section establishes the requirements for using mammography systems and x-ray machines for interventional breast radiography.

(1) Requirements for the registration of a person using radiation machines for mammography.

(A) A person must not use radiation machines except as authorized in a certificate of registration issued by the Department of State Health Services (department) as specified in 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.

[~~(1) This section provides for the certification of mammography systems and mammography machines used for interventional breast radiography. No person shall use radiation machines for mammography of humans or for interventional breast radiography except as authorized in a certification issued by the agency in accordance with the requirements of this section. Certification by this agency includes certification of mammography systems and facilities that have received accreditation by the agency accreditation body or by another United States Food and Drug Administration (FDA)-approved accreditation body and certification of mammography machines used for interventional breast radiography.~~]

(2) Mammography [~~The use of all mammography~~] machines certified under [~~in accordance with~~] this section must [~~shall~~] be used [~~by or~~] under the supervision of a physician licensed by the Texas Medical Board.

(3) Requirements for specific record keeping and general provisions for records and reports.

(b) Scope.

(1) This section applies to a person who receives, possesses, uses, or transfers radiation machines in mammography facilities. The facility is responsible for the administrative control and oversight of the mammography systems or x-ray machines used for interventional breast radiography.

(2) [~~(1)~~] In addition to the requirements of this section, all facilities [~~registrants~~] are subject to the requirements of:

(A) §289.203 of this chapter [~~title~~] (relating to Notices, Instructions, and Reports to Workers; Inspections);[~~,~~]

(B) §289.204 of this chapter [~~title~~] (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services);[~~,~~]

(C) §289.205 of this chapter [~~title~~] (relating to Hearing and Enforcement Procedures);[~~,~~]

(D) §289.226 of this subchapter [~~title~~] (relating to Registration of Radiation Machine Use and Services);[~~, and~~]

(E) §289.231 of this subchapter [~~title~~] (relating to General Provisions and Standards for Protection Against Machine-Produced Radiation); and

(F) 21 Code of Federal Regulations (CFR) Part 900, except for facilities subject to subsection (w) of this section. [~~Mammography facilities choosing to be accredited by the agency accreditation body will be subject to §289.234 of this title (relating to Mammography Accreditation).~~]

(3) [~~(2)~~] The procedures as specified [~~found~~] in §289.205 of this chapter relating to [~~title for~~] modifications, suspensions, revocations, denials, and hearings regarding certificates of registration are applicable to certifications issued by the department [~~agency~~].

(4) [~~(3)~~] This section does not apply to an entity under the jurisdiction of the federal government.

(5) [~~(4)~~] An entity, [~~that is a "covered entity" as that term is~~] defined in [~~HIPAA (~~]the Health Insurance Portability and Accountability Act of 1996 (HIPAA) as a "covered entity" under[~~,~~] 45 [~~Code of Federal Regulations (~~]CFR[~~),~~] Parts 160 and 164[~~)~~], may be subject to privacy standards governing how information identifying [~~that identifies~~] a patient can be used and disclosed. Failure to follow HIPAA requirements may result in the department referring [~~making a referral of~~] a potential violation to the United States Department of Health and Human Services.

(c) Prohibitions.

(1) The department prohibits the use of radiographic equipment designed for general purpose or special non-mammography procedures for mammographic imaging. This includes systems that have been modified or equipped with special attachments for mammography.

(2) The department prohibits the use of mammography machines posing a significant threat or danger to occupational and public health and safety, as specified in §289.205 and §289.231 of this chapter.

(3) The department prohibits exposing an individual to the useful beam, except for healing arts imaging ordered by a practitioner. This provision specifically prohibits intentional exposure of an individual for:

(A) training, demonstration, or other non-healing arts purposes;

(B) healing arts screening, or self-referral mammography except as authorized by subsection (r) of this section; and

(C) research, except as authorized by subsection (s) of this section.

(4) The department prohibits remote operation of radiation machines.

(d) Exemptions.

(1) Mammography machines or cabinet x-ray machines used exclusively for examination of breast biopsy specimens are exempt from the requirements of this section. These machines are required to meet applicable provisions of §289.226 and §289.228 of this subchapter (relating to Radiation Safety Requirements for Industrial Radiation Machines).

(2) Machines used exclusively for interventional breast radiography are exempt from the requirements of this section except for those listed in subsection (w) of this section. These machines are not required to be accredited by a United States Food and Drug Administration (FDA)-approved accreditation body (AB).

(3) Loaner machines as described in subsection (g)(6) of this section are exempt from the inspection requirements in subsection (v)(1) of this section. These machines are not required to be accredited by an AB.

(4) Mammography machines with investigational device exemptions as described in subsection (s) of this section and used in clinical studies are exempt from the requirements of this chapter. These machines are not required to be accredited by an AB.

(5) All mammography and interventional breast radiography facilities are exempt from the posting of radiation area requirements of §289.231 of this subchapter if the operator has continuous surveillance and controls access to the radiation area.

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

(1) Accreditation--The approved use of a mammography machine by an AB [~~An approval of a mammography machine within a mammography facility by an accreditation body. A facility may be accredited by the agency accreditation body or another FDA-approved accreditation body~~].

(2) Act--Texas Radiation Control Act, Health and Safety Code[~~,~~] Chapter 401.

(3) Action limit--The minimum or maximum value of a quality assurance (QA) measurement representing acceptable performance. Values less than the minimum or greater than the maximum action limit indicate [~~that~~] corrective action must be taken by the facility.

(4) Additional mammography review (AMR)--A [~~(includes targeted clinical image reviews)--At the request of the agency certification body or an FDA-approved accreditation body, a~~] review [~~by the FDA-approved accreditation body~~] of clinical images and other relevant facility information necessary to assess compliance [~~conformation~~] with [~~the~~] accreditation standards. [~~The reviews include the following:~~]

[~~(A) clinical image review with interpretation; or~~]

[~~(B) clinical image review without interpretation.~~]

(5) Adverse event--An undesirable experience associated with mammography activities [~~within the scope of this section~~]. Adverse events include [~~but are not limited to~~]:

(A) poor image quality;

(B) failure to send mammography reports within 30 days to the referring physician or in a timely manner to the self-referred patient; and

(C) use of personnel who do not meet the applicable requirements of subsection (h) [~~(r)~~] of this section.

(6) Air kerma--The kinetic energy released in air by ionizing radiation. Kerma is the quotient of dE by dM, where dE is the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles in air of mass dM. The System International (SI) unit of air kerma is joule per kilogram, and the special name for the unit of kerma is gray (Gy) [~~Agency accreditation body--For the purpose of this section, the agency as approved by the FDA under Title 21, CFR, §900.3(d) to accredit mammography facilities in the State of Texas~~].

(7) American Registry of Radiologic Technologists - Radiography (ARRT(R))--the credential issued by the American Registry of Radiologic Technologists in radiography [~~Agency certifying body--For the purpose of this section, the agency, as approved by FDA, under Title 21, CFR, §900.21, to certify facilities within the State of Texas to perform mammography services~~].

[~~(8) Air kerma--The kerma in a given mass of air. The unit used to measure the quantity of air kerma is the Gray (Gy). For x-rays with energies less than 300 kiloelectronvolts (keV), 1 Gy = 100 rad. In air, 1 Gy of absorbed dose is delivered by 114 roentgens (R) of exposure.~~]

(8) [~~(9)~~] Automatic exposure control (AEC)--A device [~~that~~] automatically controlling [~~controls~~] one or more technique factors [~~in order~~] to obtain the [~~at preselected locations a~~] required quantity of radiation at preselected locations.

(9) [~~(10)~~] Average glandular dose--The average absorbed dose [~~accruing~~] to the glandular tissue of the breast.

(10) [~~(11)~~] Beam-limiting device--A device providing [~~that provides~~] a means to restrict the dimensions of the x-ray field.

(11) [~~(12)~~] Breast implant--A prosthetic device implanted in the breast.

(12) [~~(13)~~] Calendar quarter--Any one of the following time periods during a given year: January 1 - March 31, April 1 - June 30, July 1 - September 30, or October 1 - December 31.

(13) [~~(14)~~] Calibration of instruments--The comparative response or reading of an instrument relative to a series of known radiation values over the range of the instrument.

(14) [~~(15)~~] Category I continuing medical education units (CMEU)--Educational activities designated as Category I and approved by the Accreditation Council for Continuing Medical Education, the American Osteopathic Association, a state medical society, or an equivalent organization.

(15) [~~(16)~~] Certification--An authorization for the use of a mammography system for mammography or x-ray [~~mammography~~] machines used for interventional breast radiography.

(16) [~~(17)~~] Clinical image--See the definition for mammogram.

(17) [~~(18)~~] Contact hour--An hour of training received through direct instruction.

(18) [~~(19)~~] Continuing education unit (CEU)--One contact hour of training.

(19) [~~(20)~~] Control panel--The [~~That~~] part of the radiation machine control upon which are mounted the [~~switches, knobs, push buttons, and other~~] hardware necessary for setting the technique factors.

(20) [~~(21)~~] Direct instruction--Instruction, including [~~that includes~~]:

(A) interaction between an instructor and student [~~face-to-face interaction between instructor(s) and student(s)~~], such as when the instructor provides a lecture, conducts demonstrations, or reviews student performance; or

(B) [~~the~~] administration and correction of student examinations by an instructor [~~instructor(s)~~] with subsequent feedback to the student [~~student(s)~~].

(21) [~~(22)~~] Direct supervision--Oversight of operations, including [~~that include~~] the following.

(A) During joint interpretation of mammograms, the supervising interpreting physician reviews, discusses, and confirms the interpretation [~~diagnosis~~] of the physician being supervised and signs the [~~resulting~~] report before it is entered into the patient's record.

(B) During performance of a mammography examination, the supervising medical radiologic technologist (MRT) is present to observe and correct, as needed, the individual [~~who is~~] performing the examination.

(C) During performance of a survey of the facility's [~~registrant's~~] equipment and QA [~~quality assurance~~] program, the supervising medical physicist is present to observe, and correct, as needed, the individual [~~who is~~] conducting the survey.

[~~(23) Established operating level--The value of a particular quality assurance parameter that has been established as an acceptable normal level by the registrant's quality assurance program.~~]

(22) [~~(24)~~] Facility--A hospital, outpatient department, clinic, radiology practice, mobile unit, an office of a physician, or other person conducting [~~that conducts~~] breast cancer screening or diagnosis through mammography activities, including [~~the following~~]:

(A) operating [~~the operation of~~] equipment to produce a mammogram;

(B) processing [~~of~~] film or digital images;

(C) interpreting [~~initial interpretation of~~] the mammogram; or

(D) maintaining the viewing conditions for [~~that~~] interpretation.

(23) [~~(25)~~] FDA-approved accreditation body (AB)--An entity approved by the FDA under [~~Title~~] 21[~~,~~] CFR[~~,~~] §900.3(d)[~~,~~] to accredit mammography facilities.

(24) [~~(26)~~] Final assessment categories--The overall final assessment of findings in a report of a mammography examination[~~,~~] classified in (j)(3)(E) of this section. [~~one of the following categories:~~]

[~~(A) "negative" indicates nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained);~~]

[~~(B) "benign" is also a negative assessment;~~]

[(C) "probably benign" indicates a finding(s) that has a high probability of being benign;]

[(D) "suspicious abnormality" indicates a finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant;]

[(E) "highly suggestive of malignancy" indicates a finding(s) that has a high probability of being malignant;]

[(F) "known biopsy proven malignancy" indicates appropriate action should be taken;]

[(G) "post procedure mammogram" indicates a mammogram to confirm the deployment and position of a breast tissue marker; or]

[(H) "incomplete" indicates there is a need for additional imaging evaluation and/or prior mammograms for comparison. Reasons why no assessment can be made shall be stated by the interpreting physician.]

(25) [(27)] First allowable time--The earliest time a resident physician is eligible to take the diagnostic radiology boards from an FDA-designated certifying body.

(26) [(28)] Formal training--Attendance and participation in direct instruction. This does not include self-study programs.

(27) [(29)] Half-value layer (HVL)--The thickness of a specified material attenuating [that attenuates] the beam of radiation to the [an] extent [such that] the exposure rate is reduced to one-half of its original value. [In this definition, the contribution of all scattered radiation, other than any that might be present initially in the beam concerned, is deemed to be excluded.]

(28) [(30)] Healing arts--Any system, treatment, operation, diagnosis, prescription, or practice for the ascertainment, cure, relief, palliation, adjustment, or correction of any human disease, ailment, deformity, injury, or unhealthy or abnormal physical or mental condition.

(29) Healthcare provider--A doctor of medicine or osteopathy, podiatrist, dentist, chiropractor, clinical psychologist, optometrist, physician assistant, or nurse practitioner authorized to practice by the state of Texas and performing within the scope of their practice as defined by state law.

(30) [(31)] Image receptor--Any device that transforms incident x-ray photons either into a visible image or into another form that can be made into a visible image by further transformations.

(31) [(32)] Institutional review board (IRB)--Any board, committee, or other group created under 45 CFR Part 46 and 21 CFR Part 56, and formally designated by an institution to review, approve the initiation of, and conduct periodic review of biomedical research involving human subjects.

(32) [(33)] Interpreting physician (IP)--A licensed physician who interprets mammographic images and who meets the requirements of subsection (h)(1) [(r)(1)] of this section.

(33) [(34)] Interventional breast radiography--Imaging of a breast during invasive interventions for localization or biopsy procedures.

(34) [(35)] Investigational device exemption--An exemption allowing an [that allows the] investigational device to be used in a clinical study [in order] to collect safety and effectiveness data required to support a Premarket Approval application or a 510(k) Premarket Notification submission to FDA.

(35) [(36)] Kerma--The sum of the initial energies of all the charged particles liberated by uncharged ionizing particles in a material of given mass.

(36) [(37)] Laterality--The designation of either the right or left breast.

(37) [(38)] Lead interpreting physician (LIP)--The interpreting physician assigned the general responsibility for ensuring [that] a facility's QA [quality assurance] program meets all [of the] requirements of subsections (k), (l), and (m) [(u), (v), and (w)] of this section.

(38) [(39)] Mammogram--A radiographic image produced through mammography.

(39) [(40)] Mammographic modality--A technology, within the scope of 42 United States Code (U.S.C.) §263b, for radiography of the breast. Examples are screen-film mammography, [and] full-field digital mammography, and digital breast tomosynthesis (DBT).

(40) [(41)] Mammography--The use of x-rays [x-radiation] to produce an image of the breast that may be used to detect the presence of pathological conditions of the breast. Mammography [For the purposes of this section, mammography] does not include radiography of the breast performed [as follows]:

(A) during invasive interventions for localization or biopsy procedures, except as specified in subsection (w) [(gg)] of this section; or

(B) using [with] an investigational mammography device as part of a scientific study conducted under the [in accordance with] FDA's investigational device exemption regulations.

(41) [(42)] Mammography machine--An assemblage of components for mammography. This includes an x-ray high-voltage generator, x-ray control, tube housing assembly, beam-limiting device, and the necessary supporting structures. Additional components functioning with the machine are considered integral parts of the system. [machine(s)--A unit consisting of components assembled for the production of x-rays for use during mammography. These include, at a minimum, the following:]

[(A) an x-ray generator;]

[(B) an x-ray control;]

[(C) a tube housing assembly;]

[(D) a beam limiting device; and]

(E) [supporting structures.]

(42) [(43)] Mammography medical outcomes audit--A systematic collection of mammography results and the comparison of those results [compared] with outcomes data.

(43) [(44)] Mammography system--A system, including [that includes the following]:

(A) an x-ray machine used as a source of radiation in producing images of breast tissue;

(B) an imaging system used for the formation of a latent image of breast tissue;

(C) an imaging-processing device for changing a latent image of breast tissue to a visual image that can be used for diagnostic purposes;

(D) a [viewing] device used for viewing and evaluating [the visual evaluation of] an image of breast tissue [if the image is produced in interpreting visual data captured on an image receptor];

(E) an MRT who meets the qualifications specified in subsection (h)(2) of this section and [~~a medical radiologic technologist who~~] performs mammography; and

(F) a physician who interprets [~~engages in~~] mammography and [~~who~~] meets the requirements specified in subsection (h)(1) of this section [~~relating to the reading, evaluation, and interpretation of mammograms~~].

(44) [~~(45)~~] Mandatory training--Additional training required by the department [~~agency certifying body~~] or AB [~~FDA-approved accreditation body~~] for IPs [~~interpreting physicians~~], MRTs [~~medical radiologic technologists~~], or medical physicists as the result of a required corrective action.

[~~(46) Mean optical density--The average of the optical densities measured using uniform, defect-free absorber thicknesses of 2, 4, and 6 centimeters (cm) with values of kilovolt peak (kVp) clinically appropriate for those thicknesses.~~]

(45) [~~(47)~~] Medical physicist--An individual who performs surveys and evaluations of mammographic equipment and facility QA [~~quality assurance~~] programs as specified in [~~accordance with~~] this section and who meets the qualifications in subsection (h)(3) [~~(r)(3)~~] of this section.

(46) [~~(48)~~] Medical radiologic technologist (MRT [~~operator of equipment~~])--An individual specifically trained in the use of radiographic equipment and the positioning of patients for radiographic examinations, who performs mammography examinations as specified in [~~accordance with~~] this section and who meets the qualifications in subsection (h)(2) [~~(r)(2)~~] of this section.

(47) [~~(49)~~] Mobile service operation--The provision of mammography machines and personnel at temporary sites to perform mammography for limited time periods.

(48) [~~(50)~~] Multi-reading--Two or more physicians interpreting the same mammogram. At least one physician must [~~shall~~] be qualified as an IP [~~interpreting physician~~].

(49) Operator--An individual who performs interventional breast mammography examinations.

(50) [~~(51)~~] Optical density (OD)--A measure of the fraction of incident light transmitted through a developed film and defined by the equation:
Figure: 25 TAC §289.230(e)(50)
[~~Figure: 25 TAC §289.230(e)(51)~~]

(51) [~~(52)~~] Patient--Any individual who undergoes a mammography examination in a facility, regardless of whether the individual [~~person~~] is referred by a physician or is self-referred.

(52) [~~(53)~~] Phantom--A test object used to simulate radiographic characteristics of compressed breast tissue and containing components modeling [~~that radiographically model~~] aspects of breast disease and cancer in a radiograph.

(53) [~~(54)~~] Phantom image--A radiographic image of a phantom.

(54) [~~(55)~~] Physical science--This includes physics, chemistry, radiation science (including medical physics and health physics), and engineering.

(55) Physician--An individual licensed by the Texas Medical Board to practice medicine under Texas Occupations Code Chapter 155.

(56) Positive mammogram--A mammogram with [~~that has~~] an overall assessment of findings that are either "suspicious" or "highly suggestive of malignancy."

[~~(57) Practitioner of the healing arts (practitioner)--For the purposes of this section, a person licensed to practice healing arts by the Texas Medical Board as a physician.~~]

(57) [~~(58)~~] Provisional certification--A certification category enabling a facility to perform mammography and obtain the clinical images needed to complete the accreditation process [~~provisional authorization described in subsection (g) of this section~~].

(58) [~~(59)~~] Qualified instructor--An individual whose training and experience prepares the qualified instructor [~~him or her~~] to carry out specified training assignments. IPs [~~Interpreting physicians~~], MRTs [~~medical radiologic technologists~~], or medical physicists who meet the requirements of subsection (h)[~~(r)~~] of this section are [~~would be~~] considered qualified instructors in their respective areas of mammography. Other examples of an individual [~~individuals~~] who may be a qualified instructor [~~instructors~~] for the purpose of providing training to meet the requirements of this section include[~~, but are not limited to,~~] instructors in a post-high school training institution and manufacturers' representatives.

(59) [~~(60)~~] Quality control (QC) technologist--An individual meeting the requirements of subsection (h)(2)[~~(r)(2)~~] of this section who is responsible for those QA [~~quality assurance~~] responsibilities not assigned to the LIP [~~lead interpreting physician~~] or to the medical physicist.

(60) [~~(61)~~] Radiation machine--see definition for [~~For the purposes of this part, radiation machine also means~~] mammography machine.

(61) [~~(62)~~] Self-referral mammography--The use of x-ray [~~x-radiation~~] to test asymptomatic women for the detection of diseases of the breasts when such tests are not specifically and individually ordered by a licensed physician.

(62) [~~(63)~~] Serious adverse event--An adverse event that may significantly compromise clinical outcomes, or an adverse event for which a facility fails to take appropriate corrective action in a timely manner.

(63) [~~(64)~~] Serious complaint--A report of a serious adverse event.

(64) [~~(65)~~] Source-to-image receptor distance (SID)--The distance from the source to the center of the input surface of the image receptor.

(65) [~~(66)~~] Standard breast--A 4.2 cm thick compressed breast consisting of 50 percent [%] glandular tissue and 50 percent [%] adipose tissue.

(66) [~~(67)~~] Survey--An on-site physics consultation and evaluation of a facility QA [~~quality assurance~~] program performed as specified in subsection (l)(5) of this section by a medical physicist meeting the requirements of subsection (h)(3) of this section.

(67) [~~(68)~~] Technique chart--A chart providing [~~that provides~~] all necessary generator control settings and geometry needed to make clinical radiographs.

(68) [~~(69)~~] Traceable to a national standard--Calibrated at either the National Institute of Standards and Technology (NIST) or at a calibration laboratory participating [~~that participates~~] in a proficiency program with NIST at least once every two years. The results of the proficiency test conducted within 24 months of calibration must [~~shall~~]

show agreement within plus or minus 3.0 percent [%] of the national standard in the mammography energy range.

[(d) Prohibitions.]

[(1) Radiographic equipment designed for general purpose or special nonmammography procedures shall not be used for mammography. This includes systems that have been modified or equipped with special attachments for mammography.]

[(2) The agency may prohibit use of mammography machines that pose a significant threat or endanger public health and safety, in accordance with §289.231 of this title and §289.205 of this title.]

[(3) Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed physician. This provision specifically prohibits intentional exposure for the following purposes:]

[(A) exposure of an individual for training, demonstration, or other non-healing arts purposes;]

[(B) exposure of an individual for the purpose of healing arts screening (self referral mammography) except as authorized by subsection (bb) of this section; and]

[(C) exposure of an individual for the purpose of research except as authorized by subsection (cc) of this section.]

[(e) Exemptions.]

[(1) Mammography machines or cabinet x-ray machines used exclusively for examination of breast biopsy specimens are exempt from the requirements of this section. These machines are required to meet applicable provisions of §289.226 of this title and §289.228 of this title (relating to Radiation Safety Requirements for Analytical and Other Industrial Radiation Machines).]

[(2) Mammography machines used exclusively for interventional breast radiography are exempt from the requirements of this section except for those listed in subsection (gg) of this section. These machines are not required to be accredited by an FDA-approved accreditation body.]

[(3) Loaner machines as described in subsection (n)(5) of this section are exempt from the inspection requirements in subsection (ff) of this section. These machines are not required to be accredited by an FDA-approved accreditation body.]

[(4) Mammography machines with investigational device exemptions as described in subsection (cc) of this section and used in clinical studies are exempt from the requirements of this chapter. These machines are not required to be accredited by an FDA-approved accreditation body.]

[(5) All mammography registrants are exempt from the posting of radiation area requirements of §289.231(x) of this title provided that the operator has continuous surveillance and access control of the radiation area.]

(f) Mammography systems certification.

(1) [(f)] Requirements for [mammography systems] certification.

(A) [(1)] A facility must [To obtain a certification, facilities shall] meet the quality standards in subsections (h) - (q) [(r) - (aa)] of this section and be accredited by an AB. To [FDA-approved accreditation body. In order to] qualify for certification, a new facility [facilities] must apply to the department [agency certifying body in accordance with the following requirements and to an FDA-approved accreditation body] and receive acceptance of an [the] accreditation application by an AB. [If the facility chooses to be accredited by the agency accreditation body, the facility shall submit the information required in this subsection and §289.234(d) of this title.]

(B) [(2)] A person who receives, possesses, uses, owns, or acquires [Each person having] a mammography machine must apply for certification as specified [shall submit an application] in [accordance with] §289.226(e) of this subchapter, relating to general requirements for application for registration, [(1) - (3) and (5) - (7) and (f)(4) - (5) of this title,] and receive certification from the department [agency certifying body] before using a [beginning use of the] mammography machine on humans.

(C) [(3)] An application for certification must [shall] be signed by the:

(i) LIP;

(ii) applicant; and

(iii) [(4)]radiation safety officer (RSO) [An application for certification may contain information on multiple mammography machines. Each mammography machine must be identified by referring to the machine's manufacturer, model name, and serial number on the control panel. If this is not a new certification, the registrant shall maintain and provide proof of current accreditation. If accreditation expires before the expiration of the certification, the registrant shall submit proof of renewed status to the agency.].

(D) [(5)] Each applicant must [shall] submit documentation of [the following]:

(i) [(A)] personnel qualifications, including dates of licensure or certification, as specified in [accordance with] subsection (h)[(r)] of this section;

(ii) [(B)] manufacturer, model name, and serial number of each mammography machine control panel;

(iii) [(C)] evidence that a medical physicist has:

(I) [(i)] [has] determined [that] each machine meets the equipment standards in subsection (i)[(s)] of this section;

(II) [(ii)] [has] performed a survey and a mammography equipment evaluation as specified in [accordance with] subsection (l)(5) and (6)[(v)(10) and (11)] of this section; and

(III) [(iii)] [has] determined [that] the average glandular dose for one craniocaudal [craniocaudal-caudal] view for each machine is less than [does not exceed] the value in subsection (i)(11)(D)[(v)(5)(F)] of this section;

(iv) [(D)] self-referral program information as specified in [accordance with] subsection (r)[(bb)] of this section, if the facility offers self-referral mammography;[and]

(v) [(E)] items required for authorization of a mobile service operation as specified in [accordance with] §289.226(g) of this subchapter, relating to application for registration of mobile service operations [title], if the facility provides a mobile service; and[.]

(vi) proof of current accreditation.

(2) [(g)] Issuance of certification [and provisional certification].

[(1)] [Certification.] A certification will be issued if the department [agency certifying body] determines the [that an] application meets the requirements of the Act and [the requirements of] this chapter. The certification authorizes the proposed operations and includes [activity in such form and contains such] conditions and limita-

tions deemed necessary by [as] the department [agency certifying body deems appropriate or necessary].

(A) The certification may include [one of the following]:

(i) [(A)] mammography systems and facilities certification, following approval of accreditation by an AB [FDA-approved accreditation body]; or

(ii) [(B)] certification of interventional breast radiography machines.

(B) [(2)] Conditions [Requirements and conditions]. The department [agency certifying body] may incorporate in the certification at the time of issuance, or [thereafter] by amendment, [such] additional requirements and conditions [with respect to the registrant's possession, use, and transfer of radiation machines subject to this chapter as it deems appropriate or necessary in order] to:

(i) [(A)] minimize danger to occupational and public health and safety;

(ii) [(B)] require additional reporting and record keeping [reports and the keeping of additional records as may be appropriate or necessary]; and

(iii) [(C)] prevent loss or theft of radiation machines subject to this section.

(C) [(3)] Additional information. The department [agency certifying body] may request[, and the registrant shall provide,] additional information after the certification has been issued to enable the department [agency certifying body] to determine whether the certification should be modified as specified in [accordance with] §289.226(r) of this subchapter, relating to renewal of certificates of registration [title].

(3) [(4)] Provisional certification [application. A new facility is eligible to apply for a provisional certification. The provisional certification will enable the facility to perform mammography and to obtain the clinical images needed to complete the accreditation process].

(A) To apply for and receive a provisional certification, a new facility must meet the requirements of this chapter and submit the necessary information to an AB [FDA-approved accreditation body. If the facility chooses to be accredited by the agency accreditation body, the facility shall submit the information required in subsection (f) of this section and §289.234(d) of this title to the agency accreditation body].

(B) [(5)] [Issuing provisional certifications.] Following the department's [agency certifying body's] receipt of the accreditation body's decision that a facility has submitted the required information, the department [agency certifying body] may issue a provisional certification to a facility if [upon determination that] the facility has satisfied the requirements of the Act and this chapter.

(i) A provisional certification is [shall be] effective for up to six months as noted on the certificate [from the date of issuance].

(ii) A provisional certification cannot be renewed, but a facility may apply for a 90-day extension of the provisional certification.[(6) Extension of provisional certification. Extension of provisional certifications shall be in accordance with the following.]

(C) [(A)] To apply for a 90-day extension to a provisional certification, a facility must [shall] submit to the AB [FDA-approved accreditation body] who issued the original certificate, a statement of actions taken [what the facility is doing] to obtain certification and evidence that there would be a significant adverse impact on access to mammography in the geographic area served if the [such] facility did not obtain an extension.

(i) [(B)] The department [agency certifying body] may issue a 90-day extension for a provisional certification if [upon determination that] the extension meets the criteria in paragraph (3)[(4)] of this subsection.

(ii) [(C)] Renewal [There can be no renewal] of a provisional certification beyond the 90-day extension is prohibited.

(4) [(7)] Reinstatement [policy].

(A) A previously certified facility that has allowed its certification to expire, [that has] been refused a renewal of its certification by the department [agency certifying body], or [that has] had its certification suspended or revoked by the department [agency certifying body], may reapply to have the certification reinstated so [that] the facility may be considered [to be] a new facility and thereby be eligible for a provisional certification.

(B) [(A)] Unless prohibited from reinstatement as specified in [under] subsection (f)(5)[(h)(5)] of this section, a facility applying for reinstatement must [shall]:

(i) contact an AB [FDA-approved accreditation body] for reapplication of [for] accreditation;

(ii) provide documentation of [fully document] its history as a previously provisionally certified or certified mammography facility, and include [including] the [following information]:

(I) name and address of the facility under which it was previously provisionally certified or certified;

(II) name of previous owner or lessor [owner/lessor];

(III) facility identification number assigned to the facility under its previous certification by the FDA or the department [agency certifying body]; and

(IV) expiration date of the most recent FDA or department [agency] provisional certification; and

(iii) justify application for reinstatement of accreditation by submitting to an AB [FDA-approved accreditation body] a corrective action plan detailing [that details] how the facility has corrected deficiencies contributing [that contributed] to the lapse [of], denial of renewal, or revocation of its certification.

(C) [(B)] The department [agency certifying body] may issue a provisional certification to the facility if the department [agency] determines [that] the facility has:

(i) [has] adequately corrected, or is in the process of correcting, pertinent deficiencies; and

(ii) [has] taken sufficient corrective action since the lapse [of], denial of renewal, or revocation of its previous certification.

(D) [(C)] After receiving the provisional certification, the facility may lawfully perform mammography while completing the requirements for accreditation and certification.

(5) [(h)] Suspension or revocation of certification.

(A) [(1)] Except as provided in subparagraph (B) of this paragraph [(2) of this subsection], the department [agency certifying body] may suspend or revoke a certification issued by the department [agency certification body] if it finds, after providing the owner or

[~~operator of the~~] facility representative with notice and an opportunity for a hearing as specified in [~~accordance with~~] §289.205 of this chapter [~~title~~], that the owner, facility representative [~~operator~~], or any employee of the facility has:

(i) [~~(A)~~] misrepresented documentation to obtain [~~has been guilty of misrepresentation in obtaining~~] the certification;

(ii) [~~(B)~~] [~~has~~] failed to comply with the requirements of this chapter;

(iii) [~~(C)~~] [~~has~~] failed to comply with requests of the department [~~agency certifying body~~] or an AB [~~FDA-approved accreditation body~~] for records, information, reports, or materials [~~that are~~] necessary to determine the continued eligibility of the facility for a certification or continued compliance with the requirements of this chapter;

(iv) [~~(D)~~] [~~has~~] refused a request of a duly designated FDA inspector, state inspector, or an AB [~~FDA-approved accreditation body~~] representative for permission to inspect the facility or the operations and pertinent records of the facility;

(v) [~~(E)~~] [~~has~~] violated or aided and abetted in the violation of any provision of or regulation promulgated pursuant to the requirements of the Act and the requirements of this chapter; or

(vi) [~~(F)~~] [~~has~~] failed to comply with prior sanctions imposed by the department as specified in [~~agency certifying body under~~] §289.205 of this chapter [~~title~~].

(B) [~~(2)~~] The department [~~agency certifying body~~] may suspend a certification of a facility before holding a hearing if it makes a finding described in subparagraph (A) [~~paragraph (1)~~] of this paragraph [~~subsection~~] and [~~also~~] determines that:

(i) [~~(A)~~] the failure to comply with requirements presents a serious risk to human health;

(ii) [~~(B)~~] the refusal to permit inspection makes immediate suspension necessary; or

(iii) [~~(C)~~] there is reason to believe [~~that~~] the violation or aiding and abetting of the violation was intentional or associated with fraud.

(C) [~~(3)~~] If the department [~~agency certifying body~~] suspends a certification as specified in subparagraph (B) of this [~~accordance with~~] paragraph [~~(2) of this subsection~~]:

(i) [~~(A)~~] the department will [~~agency certifying body shall~~] provide the facility with an opportunity to request [~~for~~] a hearing as specified in [~~under~~] §289.205 of this chapter [~~not later than 60 days from the effective date of this suspension~~]; and

(ii) [~~(B)~~] the suspension will [~~shall~~] remain in effect until it is determined by the department [~~agency certifying body determines~~] that the:

(I) [~~(i)~~] allegations of violations or misconduct were not substantiated;

(II) [~~(ii)~~] violations of requirements have been corrected to the department's [~~agency certifying body's~~] satisfaction; or

(III) [~~(iii)~~][~~the~~] certification is revoked as specified in subparagraph (D) [~~accordance with paragraph (4)~~] of this paragraph [~~section~~].

(D) [~~(4)~~] After providing a hearing as specified in §289.205 of this chapter [~~accordance with paragraph (3)(A) of this subsection~~], the department [~~agency certifying body~~] may revoke the certification if it is determined by the department [~~agency determines~~] that the facility:

(i) [~~(A)~~] is unwilling or unable to correct violations that were the basis for suspension; or

(ii) [~~(B)~~] has engaged in fraudulent activity to obtain or continue certification.

(E) [~~(5)~~] If a facility's certification was revoked based on [~~on the basis of~~] an act described in §289.205 of this chapter, a [~~title, no~~] person who owned or operated that facility at the time the act occurred is prohibited from owning [~~may own or operate~~] a mammography facility for [~~within~~] two years following [~~of~~] the [~~date of~~] revocation date.

(6) [~~(i)~~] Appeal of adverse accreditation or reaccreditation decisions preventing [~~that preclude~~] certification or recertification.

(A) [~~(1)~~] The appeal process described in this paragraph [~~subsection~~] is only available [~~only~~] for adverse accreditation or reaccreditation decisions preventing [~~that preclude~~] certification by the department. If the department suspends or revokes a certificate [~~agency certifying body. Agency certifying body decisions to suspend or revoke certificates that are~~] already in effect, it will be handled as specified in [~~accordance with~~] subsection (f)(5) [~~(h)~~] of this section.

(B) [~~(2)~~] If [~~Upon learning that~~] a facility has failed to become accredited or reaccredited, the department [~~agency certifying body~~] will notify the facility that the department [~~agency certifying body~~] is unable to certify the [~~that~~] facility without proof of accreditation.

(C) [~~(3)~~] A facility that has been denied accreditation or reaccreditation and cannot achieve satisfactory resolution of an adverse accreditation decision through the AB's [~~FDA-approved accreditation body's~~] appeal process is entitled to further appeal to the FDA.

(D) [~~(4)~~] A facility cannot perform mammography services while an adverse accreditation decision is being appealed.

(7) [~~(j)~~] Denial of certification.

(A) [~~(1)~~] The department [~~agency certifying body~~] may deny the application if the department [~~agency certifying body~~] has reason to believe that:

(i) [~~(A)~~] the facility will not be operated as specified in [~~accordance with~~] the provisions of subsections (h) - (q)[~~(r) - (aa)~~] of this section;

(ii) [~~(B)~~] the facility will not permit inspections or provide access to records or information [~~in a~~] timely [~~fashion~~];

(iii) [~~(C)~~] made a materially [~~any material~~] false statement in the application or any statement of fact required under provision of the Act [~~was made~~];

(iv) [~~(D)~~] conditions revealed by such application or statement of fact or any report, record, inspection, or other means that would warrant the department [~~agency certification body~~] to refuse to grant a certification of mammography facility on an original application; or

(v) [~~(E)~~] the facility failed to observe any of the terms and conditions of the Act, this chapter, or order of the department [~~agency~~].

(B) [~~(2)~~] Before the department [~~agency certification body~~] denies an application for certification, the department must [~~agency shall~~] give notice of the denial, the facts warranting the denial, and [~~shall~~] afford the applicant an opportunity for a hearing in

accordance with §289.205(h) of this chapter [~~title~~]. If no request for a hearing is received by the director of the Radiation Control Program within 30 days of date of receipt of the notice, the department [~~agency~~] may proceed to deny. The applicant must bear [~~shall have~~] the burden of proof showing cause why the application should not be denied.

(C) [~~(3)~~] If the department [~~agency certifying body~~] denies an application for certification from [~~by~~] a facility that has received accreditation from an AB [~~FDA-approved accreditation body~~], the department will [~~agency certifying body shall~~] provide the facility with a written statement of the grounds on which the denial is based.

(8) [~~(k)~~] Appeals of a certification denial [~~Appeals of denial of certification~~].

(A) [~~(1)~~] The appeals procedures described in this paragraph [~~subsection~~] are available only to facilities that are denied certification by the department [~~agency certifying body~~] after they have been accredited by an AB [~~FDA-approved accreditation body. Appeals for facilities that have failed to become accredited with the agency accreditation body shall be in accordance with §289.234(h) of this title~~].

(B) [~~(2)~~] A facility that has been denied certification may request reconsideration and appeal the department's [~~of the agency certifying body's~~] determination as specified in [~~accordance with~~] the applicable provisions of §289.205(h) of this chapter [~~title~~].

(9) [~~(l)~~] Modification of certification. Modification of a certification will follow the requirements in §289.226(s) of this subchapter, relating to modification, suspension, and revocation of certificates of registration [~~shall be in accordance with §289.226(r) of this title~~].

(10) [~~(m)~~] Specific terms and conditions of certification. Specific terms and conditions of certification will [~~shall~~] be as specified in [~~accordance with~~] §289.226(l) of this subchapter, relating to terms and conditions of certificates of registration [~~title~~].

(11) Renewal of certification.

(A) A certification for a mammography system is valid for three years from the date of issuance unless the certification of the facility is suspended or revoked before such deadlines.

(B) A mammography facility filing an application for renewal of their certification must meet the quality standards in subsections (h) - (q) of this section and be accredited by an AB. The renewal must include a list of all IPs, MRTs, and medical physicists practicing at the facility and must be filed as specified in:

(i) §289.226(r) of this subchapter, relating to renewal of certificates of registration;

(ii) §289.204(d) and (g) of this chapter, relating to payment of fees;

(iii) subsection (f)(1)(C) of this section; and

(iv) subsection (f)(1)(D)(i) of this section.

(C) A mammography facility filing an application for renewal before the existing certification expires may continue to perform mammography until the application status has been determined by the department.

(D) A facility with mammography machines used for interventional breast radiography must apply for renewal as specified in subsection (w)(5) of this section and pay the fee specified in §289.204(d) of this chapter.

(12) Expiration of certification.

(A) Each certification expires at the end of the day on the expiration date listed on the mammography certificate unless the certificate is suspended or revoked before the expiration date. Expiration of the certification does not relieve the facility of the requirements of this chapter.

(B) If a facility does not apply for renewal of the certification as specified in paragraph (11) of this subsection, as applicable, the facility must:

(i) terminate use of all mammography machines;

(ii) notify the department in writing of the storage location of mammography images and address how the requirements of subsection (j)(7)(E) of this section will be met;

(iii) pay any outstanding fees specified in §289.204 of this chapter; and

(iv) submit a record of the disposition of the mammography machine to the department.

(13) Termination of certification. When a facility decides to terminate all activities involving mammography machines authorized under the certification, the facility must:

(A) notify the department and the AB within 30 days;

(B) request termination of the certification in writing;

(C) pay any outstanding fees specified in §289.204 of this chapter;

(D) notify the department, in writing, of the storage location of mammography images and address how the requirements of subsection (j)(7)(E) of this section will be met; and

(E) submit a record of the disposition of the mammography machine to the department.

(g) [~~(n)~~] Responsibilities of the facility [~~registrant~~].

(1) In addition to the requirements of §289.226(m)(3) - (7) of this subchapter, relating to responsibilities of the registrant, the facility must [~~title, a registrant shall~~] notify the department [~~agency certifying body~~] in writing, within 30 days, of [~~prior to~~] any changes rendering [~~that would render~~] the information contained in the application or the certification inaccurate, including the[~~. These include but are not limited to the following~~]:

(A) name of the facility; [~~and~~]

(B) mailing address;

(C) [~~(B)~~] street address where the machine is [~~machine(s) will be~~] used; [~~and~~]

[~~(C) mammography machines.~~]

(D) addition or removal of any mammography machine; or

(E) name and qualifications of the RSO or LIP.

(2) Before [~~Prior to~~] employing an individual [~~the individuals~~] listed in subparagraphs (A) - (E) of this paragraph, the facility [~~registrant~~] is required to verify and maintain a copy [~~copies~~] of the [~~their~~] qualifications of the [~~. If a facility makes a change in the RSO, the qualifications of the RSO shall be submitted to the agency within 30 days of such change. Written notification of a change in any of the following in subparagraphs (B) - (E) of this paragraph is required within 30 days of such change~~]:

(A) RSO [~~radiation safety officer~~];

(B) LIP [~~lead interpreting physician~~];

(C) IP [~~interpreting physicians~~];

(D) MRT [~~medical radiologic technologists~~]; or

(E) medical physicist.

(3) A facility [~~Registrants~~] utilizing an IP [~~interpreting physicians~~] or MRT [~~technologists~~] from a temporary staffing service must [~~shall~~] verify and maintain copies of the qualifications of these individuals for inspection by the department [~~agency. The registrant does not need to notify the agency certifying body unless these personnel will be at the facility for a period exceeding four weeks~~].

(4) For accreditation, a facility adding or replacing a mammography machine must have a current accreditation or apply to the AB, unless exempted by subsection (d) of this section [~~All mammography facilities installing new or replacement mammography machines shall have either current accreditation or have submitted an application to an FDA-approved accreditation body for review unless exempted by subsection (e)(1) - (3) of this section. A mammography machine shall not be used to perform mammograms if an application for accreditation for that machine has been denied, or if the accreditation has been suspended or expired~~].

(5) For certification, a facility with an existing certificate may begin using a new or replacement machine before receiving an updated certificate if the facility submits to the department and AB an application with a medical physicist report as specified in subsection (l)(5) and (6) of this section [~~A facility with an existing certification may begin using a new or replacement machine before receiving an updated certification if the registrant submits to the agency certifying body and to the FDA-approved accreditation body, documentation with a medical physicist's report in accordance with subsection (v)(10) and (11) of this section, verifying compliance of the new machine with this section. The medical physicist's report is required prior to using the machine on patients~~].

(6) Loaner mammography machines may be used on patients for 60 days without adding the mammography machine to the certification. A medical physicist's report verifying compliance of the loaner mammography machine with this section must [~~shall~~] be completed before [~~prior to~~] use on patients. The results of the survey must be submitted to the department [~~agency~~] with a cover letter indicating period of use. If the use period will exceed 60 days, the facility must [~~shall~~] add the mammography machine to its certification and a fee will be assessed.

(7) Records of training and experience and all other records required by this section must [~~shall~~] be maintained for review as specified in [~~accordance with~~] subsection (x) [~~(ee)~~] of this section.

[~~(o) Renewal of certification.~~]

[~~(1) A certification for a mammography system is valid for three years from the date of issuance unless the certification of the facility is suspended or revoked prior to such deadlines.~~]

[~~(2) A mammography facility filing an application for renewal of their certification shall meet the quality standards in subsections (r) - (aa) of this section and be accredited by an FDA-approved accreditation body. The renewal shall be filed in accordance with the following:~~]

[~~(A) §289.226(e)(1) - (3), (5) and (7) of this title and §289.226(f)(4) and (5) of this title;~~]

[~~(B) signatures of appropriate personnel in accordance with subsection (f)(3) of this section;~~]

[~~(C) machine information and medical physicist's survey in accordance with subsection (f)(5)(B) and (C) of this section;~~]

[~~(D) fees in accordance with §289.204 of this title; and~~]

[~~(E) a list of all interpreting physicians, medical radiologic technologists and medical physicists practicing at the facility.~~]

[~~(3) A mammography facility filing an application for renewal before the existing certification expires may continue to perform mammography until the application status has been determined by the agency.~~]

[~~(4) A facility with mammography machines used for interventional breast radiography shall file an application for renewal in accordance with subsection (gg)(8) of this section and pay the fee required by §289.204 of this title.~~]

[~~(p) Expiration of certification.~~]

[~~(1) Except as provided by subsection (o) of this section, each certification expires at the end of the day in the month and year stated on the mammography certificate. Expiration of the certification does not relieve the registrant of the requirements of this chapter.~~]

[~~(2) If a registrant does not submit an application for renewal of the certification under subsection (o) of this section, as applicable, the registrant shall on or before the expiration date specified in the certification:~~]

[~~(A) terminate use of all mammography machines;~~]

[~~(B) notify the agency certifying body in writing of the film storage location of mammography patients' films and address how the requirements of subsection (t)(4)(D) of this section will be met;~~]

[~~(C) pay any outstanding fees in accordance with §289.204 of this title; and~~]

[~~(D) submit a record of the disposition of the mammography machine(s) to the agency certifying body. If the machine(s) was transferred, include to whom it was transferred.~~]

[~~(q) Termination of certification. When a registrant decides to terminate all activities involving mammography machines authorized under the certification, the registrant shall:~~]

[~~(1) notify the agency certifying body and the FDA-approved accreditation body immediately;~~]

[~~(2) request termination of the certification in writing;~~]

[~~(3) pay any outstanding fees in accordance with §289.204 of this title;~~]

[~~(4) notify the agency certifying body, in writing, of the film storage location of mammography patients' films and address how the requirements of subsection (t)(4)(D) of this section will be met; and~~]

[~~(5) submit a record of the disposition of the mammography machine(s) to the agency certifying body. If the machine(s) was transferred, include to whom it was transferred.~~]

(h) [~~(r)~~] Personnel qualifications. The following requirements apply to all personnel involved in any aspect of mammography, including the production and interpretation of mammograms.

(1) Interpreting physician. Each physician interpreting mammograms must [~~shall~~] hold a current Texas license issued by the Texas Medical Board and meet the following qualifications.

(A) Initial qualifications. Before interpreting mammograms independently, the physician must [~~shall~~]:

(i) be certified by the American Board of Radiology, the American Osteopathic Board of Radiology, or one of the other bodies approved by the FDA to certify IPs [~~interpreting physicians~~] or have at least three months of documented formal training in the interpretation of mammograms and in topics related to mammography as specified in subparagraph (B) of this paragraph [~~accordance with subsection (hh)(2) of this section~~];

(ii) have completed [~~had~~] a minimum of 60 hours of documented category I CMEUs in mammography and at [~~. At~~] least 15 of the 60 hours must [~~shall~~] have been acquired within three years immediately before [~~prior to~~] the date [~~that~~] the physician became qualified as an IP (hours [~~interpreting physician. Hours~~] spent in residency specifically devoted to mammography will be equivalent to category I CMEUs and accepted if documented in writing by the appropriate representative of the training institution); and

(iii) have interpreted or multi-read, under the direct supervision of an IP [~~interpreting physician~~], at least 240 mammographic examinations within the six-month period immediately before [~~prior to~~] the date that the physician qualifies as an IP. The supervising interpreting physician's presence is not required when the physician being supervised makes the initial interpretation. However, the supervising physician must review and, if necessary, correct the final interpretation before it is given to the patient [~~interpreting physician~~].

(B) Subjects to be included in mammography training for interpreting physicians must include:

(i) radiation physics, including radiation physics specific to mammography;

(ii) radiation effects;

(iii) radiation protection; and

(iv) interpretation of mammograms. This must be under the direct supervision of a physician who meets the requirements of paragraph (1) of this subsection.

(C) [~~(B)~~] Exemptions.

(i) A physician [~~Physicians who~~] qualified as an IP as specified [~~interpreting physicians~~] in [~~accordance with~~] the requirements of §289.230 that were in effect before [~~prior to~~] April 28, 1999, or any other equivalent state or federal requirements in effect before [~~prior to~~] April 28, 1999, is [~~are~~] considered to have met the initial requirements of subparagraph (A) of this paragraph.

(ii) Physicians who have interpreted or multi-read at least 240 mammographic examinations under the direct supervision of an IP [~~interpreting physician~~] in any six-month [~~six month~~] period during the last two years of a diagnostic radiology residency and who became board certified at the first allowable time, are exempt from subparagraph (A)(iii) of this paragraph.

(D) [~~(C)~~] Continuing education. [~~and experience. The time period for completing continuing education is a 36-month period and the time period for completing continuing experience is a 24-month period. These periods begin when a physician completes the requirements to become an interpreting physician in subparagraph (A) of this paragraph. The facility shall choose one of the dates in clause (i) of this subparagraph to determine the 36-month continuing education period and one of the dates in clause (ii) of this subparagraph to determine the 24-month continuing experience period. Each interpreting physician shall maintain qualifications by meeting the following requirements:~~]

(i) Each IP must maintain continuing education by completing at least 15 category I mammography CMEUs, in a rolling 36-month period, by participating in or teaching mammography courses. CMEUs earned through teaching a specific course can only be counted once during the 36-month period. [~~participating in education programs by completing at least 15 category I CMEUs in mammography or by teaching mammography courses. CMEUs earned through teaching a specific course can be counted only once during the 36-month period. The continuing education must be completed in the 36 months immediately preceding:~~]

(I) The period for the initial continuing education begins when a physician completes the requirements in subparagraph (A) of this paragraph. [~~the date of the registrant's annual inspection;~~]

(II) The facility chooses one of the dates in subclause (III) of this clause to determine the start of the subsequent 36-month continuing education period. [~~the last day of the calendar quarter preceding the inspection; or~~]

(III) Continuing education must be completed in the 36 months immediately preceding: [~~any date in between the two;~~]

(-a-) the date of the facility's inspection;

(-b-) the last day of the calendar quarter preceding the inspection; or

(-c-) any date in between the two.

(ii) Each IP must complete at least eight hours of training in any mammography modality in which the IP has not been previously trained, before independently using the new modality. [~~interpreting or multi-reading at least 960 mammographic examinations that must be completed during the 24 months immediately preceding:~~]

[(I) ~~the date of the registrant's annual inspection;~~]

[(II) ~~the last day of the calendar quarter preceding the inspection; or~~]

[(III) ~~any date in between the two; and~~]

(iii) ~~accumulating at least eight hours of CMEUs in any mammography modality in which the interpreting physician has not been previously trained, prior to independently using the new modality.~~

(E) Continuing experience.

(i) Each IP must maintain continuing experience by interpreting or multi-reading at least 960 mammographic examinations.

(ii) The period for the initial continuing experience begins when a physician completed the requirements in subparagraph (A) of this paragraph.

(iii) The facility chooses one of the dates in clause (iv) of this subparagraph to determine the start of the subsequent 24-month continuing experience period.

(iv) Continuing experience must be completed in the 24 months immediately preceding:

(I) the date of the facility's inspection;

(II) the last day of the calendar quarter preceding the inspection; or

(III) any date in between the two.

(F) [~~(D)~~] Re-establishing qualifications. Before resuming independent interpretation of mammograms, an IP failing [~~interpreting physicians who fail~~] to maintain the required continuing education or experience must [~~requirements shall~~] re-establish their

qualifications by completing one or both of the following requirements, as applicable:

(i) obtain [~~a sufficient number of~~] additional category I CMEUs to bring the [~~their~~] total up to [~~the~~] 15 category I CMEU credits required in the previous 36 months; [~~and/or~~]

(ii) within the six months immediately before [~~prior to~~] resuming independent interpretation and under the direct supervision of a physician qualified as an IP [~~interpreting physician~~], interpret or multi-read one of the following, whichever is less:

(I) at least 240 mammographic examinations; or

(II) additional [~~a sufficient number of~~] mammographic examinations to bring the total up to 960 examinations for the prior 24 months.

(G) [~~(E)~~] Additional mandatory training. Additional mandatory training may be required by the department [~~agency~~] based on the recommendations of an AB, the department, [~~the American College of Radiology~~] or the FDA. Training is [~~Such training will be~~] developed on a case-by-case [~~case by case~~] basis.

(i) The department [~~agency~~] may require pre-approval of any additional mandatory training.

(ii) Documentation of the additional mandatory training must [~~shall~~] be submitted for review by the date specified by the department [~~agency~~].

(iii) Records of all additional mandatory training must [~~shall~~] be maintained by the facility [~~registrant~~] for inspection by the department as specified [~~agency~~] in [~~accordance with~~] subsection (x)(3)[~~(ee)(3)~~] of this section.

(2) Medical radiologic technologists (MRTs [~~operators of equipment~~]). Each individual [~~person~~] performing mammographic examinations must maintain current credentials as an ARRT(R) and MRT as specified in [~~shall have current certification as a medical radiologic technologist under~~] the Medical Radiologic Technologist Certification Act, Texas Occupations Code[~~,~~] Chapter 601, and must [~~shall~~] meet the following qualifications.

(A) Initial requirements. Before performing mammographic examinations, the MRT must [~~operator of equipment shall have~~]:

(i) complete [~~completed~~] a minimum of 40 contact hours of training as specified [~~outlined~~] in subparagraph (B) [~~subsection (hh)(1)~~] of this paragraph [~~section~~] by a qualified instructor; and

(ii) perform [~~performed~~] a minimum of 25 mammographic examinations under the direct supervision of an individual qualified as specified in [~~accordance with the requirements of~~] this paragraph. The 25 mammographic examinations may be obtained concurrently with the 40 contact hours of training specified in clause (i) of this subparagraph but must [~~shall~~] not exceed 16 hours of the 40 contact hours.

(B) Subjects to be included in mammography training for an MRT must include the following:

(i) breast anatomy and physiology;

(ii) positioning and compression;

(iii) QA/QC techniques;

(iv) imaging of patients with breast implants; and

(v) at least eight hours of training in each mammography modality to be used by the MRT in performing mammography examinations.

(C) [~~(B)~~] Exemptions. MRTs [~~Equipment operators who~~] qualified [~~as medical radiologic technologists~~] to perform mammography as specified in [~~accordance with~~] the requirements of §289.230 that were in effect before [~~prior to~~] April 28, 1999, and any other federal requirements in effect before [~~prior to~~] April 28, 1999, are considered to have met the initial requirements of subparagraph (A) of this paragraph.

(D) [~~(C)~~] Continuing education. [~~and experience. The time period for completing continuing education is a 36-month period and the time period for completing continuing experience is a 24-month period. The period for continuing education begins when a technologist completes the requirements in subparagraph (A) of this paragraph. The period for continuing experience begins when a technologist completes the requirements in subparagraph (A) of this paragraph, or April 28, 1999, whichever is later. The facility shall choose one of the dates in clause (i) of this subparagraph to determine the 36-month continuing education period and one of the dates in clause (ii) of this subparagraph to determine the 24-month continuing experience period. Each medical radiologic technologist shall maintain qualifications by meeting the following requirements:~~]

(i) Each MRT must maintain continuing education by completing at least 15 mammography CEUs, in a rolling 36-month period, by participating in or teaching mammography courses. CEUs earned through teaching a specific course can only be counted once during the 36-month period. [~~participating in education programs by completing at least 15 CEUs in mammography or by teaching mammography courses. CEUs earned through teaching a specific course can be counted only once during the 36-month period. The continuing education must be completed in the 36 months immediately preceding:~~]

(I) The period for the initial continuing education begins when an MRT completes the requirements in subparagraph (A) of this paragraph, or April 28, 1999, whichever is later. [~~the date of the registrant's annual inspection;~~]

(II) The facility chooses one of the dates in subclause (III) of this clause to determine the start of the subsequent 36-month continuing education period. [~~the last day of the calendar quarter preceding the inspection; or~~]

(III) Continuing education must be completed in the 36 months immediately preceding: [~~any date in between the two;~~]

(-a-) the date of the facility's inspection;

(-b-) the last day of the calendar quarter preceding the inspection; or

(-c-) any date in between the two.

(ii) Each MRT must complete at least eight hours of CEUs in any mammography modality in which the MRT has not been previously trained, before independently using the new modality. [~~performing a minimum of 200 mammographic examinations that must be completed during the 24 months immediately preceding:~~]

~~*[(I)* the facility's annual inspection;]~~

~~*[(II)* the last day of the calendar quarter preceding the inspection; or]~~

~~*[(III)* any date in between the two; and]~~

~~*[(iii)* accumulating at least eight hours of CEUs in any mammography modality in which the medical radiologic technologist has not been previously trained, prior to independently using the new modality.]~~

(E) Continuing experience.

(i) Each MRT must maintain continuing experience by completing 200 mammographic examinations.

(ii) The period for the initial continuing experience begins when an MRT completes the requirements in subparagraph (A) of this paragraph.

(iii) The facility chooses one of the dates in clause (iv) of this subparagraph to determine the start of the subsequent 24-month continuing experience period.

(iv) Continuing experience must be completed in the 24 months immediately preceding:

(I) the date of the facility's inspection;

(II) the last day of the calendar quarter preceding the inspection; or

(III) any date in between the two.

(F) [~~(D)~~] Requalification. Before resuming independent performance of mammograms, MRTs [~~medical radiologic technologists~~] who fail to maintain the continuing education or experience requirements must [~~shall~~] re-establish their qualifications by completing one or both of the following requirements, as applicable:

(i) obtain [~~obtaining a sufficient number of~~] additional CEUs to bring the [~~their~~] total up to [~~the~~] 15 CEU credits required in the previous 36 months;[~~, at least six of which shall be related to each modality used by the technologist in mammography; and/or~~]

(ii) perform [~~performing~~] a minimum of 25 mammographic examinations under the direct supervision of a qualified MRT [~~medical radiologic technologist~~].

(G) [~~(E)~~] Additional mandatory training. Additional mandatory training may be required by the department [~~agency~~] based on the recommendations of an AB, the department, [~~the American College of Radiology~~] or the FDA. Training is [~~Such training will be~~] developed on a case-by-case [~~ease by ease~~] basis.

(i) The department [~~agency~~] may require pre-approval of any additional mandatory training.

(ii) Documentation of the additional mandatory training must [~~shall~~] be submitted for review by the date specified by the department [~~agency~~].

(iii) Records of all additional mandatory training must [~~shall~~] be maintained by the facility [~~registrant~~] for inspection by the department as specified in [~~agency in accordance with~~] subsection (x)(3)[~~(ee)(3)~~] of this section.

(3) Medical physicist. Each medical physicist performing mammographic surveys, evaluating mammographic equipment, or providing oversight of the facility QA [~~quality assurance~~] program as specified in [~~accordance with~~] subsection (k) [~~(u)~~] of this section must [~~, shall~~] hold a current Texas license under the Medical Physics Practice Act, Texas Occupations Code[~~,~~] Chapter 602, in diagnostic radiological physics. The medical physicist must [~~and~~] be registered with the department [~~agency~~] or employed by an entity registered with the department [~~agency~~], as specified in [~~accordance with~~] §289.226(j) of this subchapter [~~title~~] and the Act, unless exempted by §289.226(d)(7) [~~(6)~~] of this subchapter [~~title~~]. Each medical physicist must [~~shall~~] meet the following qualifications.

(A) Initial qualifications. Before performing surveys and evaluating mammographic equipment independently, the medical physicist must have [~~shall~~]:

(i) [~~have~~] a master's [~~masters~~] degree or higher in a physical science from an accredited institution, with no less than 20 semester hours, 30 quarter hours, or equivalent [~~(30 quarter hours)~~] of college undergraduate or graduate level physics;

(ii) [~~have~~] 20 contact hours of documented specialized training in conducting surveys of mammography facilities; and

(iii) [~~have~~] experience conducting surveys of at least one mammography facility and a total of at least 10 [~~ten~~] mammography machines. Experience [~~After April 28, 1999, experience~~] conducting surveys must be acquired under the direct supervision of a medical physicist who meets the requirements of subparagraphs (A), [~~and~~] (C), and (D) of this paragraph. No more than one survey of a specific machine within a period of 60 days can be counted towards the total mammography machine survey requirement.

(B) Alternative initial qualifications. Individuals who qualified as a medical physicist as specified in [~~accordance with~~] the requirements of this section that were in effect before [~~prior to~~] April 28, 1999, or any other equivalent state or federal requirements in effect before [~~prior to~~] April 28, 1999, and have met the following additional qualifications before [~~prior to~~] April 28, 1999, are determined to have met the initial qualifications of subparagraph (A) of this paragraph:

(i) a bachelor's degree or higher in a physical science from an accredited institution with no less than 10 [~~ten~~] semester hours or equivalent of college undergraduate or graduate level physics;

(ii) 40 contact hours of documented specialized training in conducting surveys of mammography facilities; and

(iii) experience conducting surveys of at least one mammography facility and a total of at least 20 mammography machines. No more than one survey of a specific machine within a period of 60 days can be counted towards the total mammography machine survey requirement. The training and experience requirements must be met after fulfilling the degree requirements.

(C) Continuing education. [~~and experience. The time period for completing continuing education is a 36-month period and the time period for completing continuing experience is a 24-month period. The period for continuing education will begin when a physicist completes the requirements in subparagraph (A) of this paragraph. The time period for continuing experience will begin when a physicist completes the requirements in subparagraph (A) of this paragraph, or April 28, 1999, whichever is later. The facility shall choose one of the dates in clause (i) of this subparagraph to determine the 36-month continuing education period and one of the dates in clause (ii) of this subparagraph to determine the 24-month continuing experience period. Each medical physicist shall maintain his/her qualifications by meeting the following requirements:~~]

(i) Each medical physicist must maintain continuing education by completing at least 15 mammography CEUs, in a rolling 36-month period, by participating in or teaching mammography courses. CEUs earned through teaching a specific course can only be counted once during the 36-month period. [~~participating in education programs, either by teaching or completing at least 15 CEUs in mammography that shall include hours of training appropriate to each mammographic modality evaluated by the medical physicist during his or her surveys. CEUs earned through teaching a specific course can be counted only once during the 36-month period. The continuing education must be completed in the 36 months immediately preceding:~~]

(I) The period for the initial continuing education begins when a medical physicist completes the requirements in subparagraph (A) of this paragraph, or April 28, 1999, whichever is later. [~~the date of the registrant's annual inspection;~~]

(II) The facility chooses one of the dates in subclause (III) of this clause to determine the start of the subsequent 36-month continuing education period. [by the last day of the calendar quarter preceding the inspection; or]

(III) Continuing education must be completed in the 36 months immediately preceding: [any date in between the two;]

(-a-) the date of the facility's inspection;

(-b-) the last day of the calendar quarter preceding the inspection; or

(-c-) any date in between the two.

(ii) Each medical physicist must also complete at least eight hours of training in any mammography modality in which the medical physicist has not been previously trained, before independently using the new modality. [performing surveys of two mammography facilities and a total of at least six mammography machines (no more than one survey of a specific facility within a ten-month period or a specific machine within a period of 60 days can be counted towards the total mammography machine survey requirement). The continuing experience must be completed during the 24 months immediately preceding:]

[*(I)* the date of the facility's annual inspection;]

[*(II)* by the last day of the calendar quarter preceding the inspection; or]

[*(III)* any date in between the two; and]

[*(iii)* accumulating at least eight hours of CEUs in any mammography modality in which the medical physicist has not been previously trained, prior to independently using the new modality.]

(D) Continuing experience.

(i) Each medical physicist must perform a survey of two mammography facilities and at least six mammography machines. No more than one survey of a specific facility within a 10-month period or a specific machine within 60 days can be counted toward the total mammography machine survey requirement.

(ii) The period for the initial continuing experience begins when a medical physicist completes the requirements in subparagraph (A) of this paragraph.

(iii) The facility chooses one of the dates in clause (iv) of this subparagraph to determine the start of the subsequent 24-month continuing experience period.

(iv) Continuing experience must be completed in the 24 months immediately preceding:

(I) the date of the facility's inspection;

(II) the last day of the calendar quarter preceding the inspection; or

(III) any date in between the two.

(E) [(D)] Re-establishing qualifications. Before resuming independent performance of surveys and equipment evaluations, medical physicists who fail to maintain the continuing education or experience requirements must [shall] reestablish their qualifications by completing one or both of the following requirements, as applicable:

(i) obtain [obtaining a sufficient number of] additional CEUs to bring the [their] total up to the 15 CEU credits required in the previous 36 months; [and/or]

(ii) perform [performing a sufficient number of] surveys, under the direct supervision of a qualified medical physicist, to bring their total up to two mammography facilities and a total of at least six mammography machines for the prior 24 months. No more than one survey of a specific machine within a period of 60 days may [shall] be counted towards the total mammography machine survey requirement.

(4) Retention of personnel records. [Records documenting the qualifications, continuing education, and experience of personnel in subsection (r)(1) - (3) shall be maintained for inspection by the agency in accordance with subsection (ee) of this section.]

(A) Facilities must maintain records of training and experience relevant to their qualifications, as specified in subsection (h)(1) - (3) of this section, for personnel who work or have worked at the facility as IPs, MRTs, or medical physicists for review by the department.

(B) Records of personnel no longer employed by the facility must be maintained for at least 24 months from the date of the departure of the employee, and these records must be available for review at the time of an annual inspection occurring during those 24 months. Personnel records must be maintained by the facility for inspection by the department as specified in subsection (x) of this section.

(i) The facility must provide copies of these personnel records to current IPs, MRTs, and medical physicists upon their request.

(ii) The facility must provide personnel records to a former employee if the former employee communicates their request within 24 months of the date of their departure.

(I) If it has been greater than 24 months and the facility has maintained those records, the facility must provide those records to former employees upon request.

(II) If a facility closes or stops providing mammography services, it must arrange for current and former personnel to access their personnel qualification records before closing. Access may be provided by a permanent transfer of records to the personnel or the transfer of the records to a facility or other entity that will provide access to these records for at least 24 months from the date of facility closure of mammography services.

(i) [(s)] Machine Requirements. Mammographic machines must meet the following requirements [Equipment standards. Only systems meeting the following standards shall be used].

(1) System design. The equipment must be [shall have been] specifically designed and manufactured for mammography and as required by [in accordance with Title] 21[,] CFR[,] §§1010.2, 1020.30, and 1020.31.

(2) A mammography machine converted from one mammographic modality to another is considered a new machine at the facility under this subsection.

(A) Before clinical use, the mammography machine must undergo a mammography equipment evaluation and demonstrate compliance with applicable requirements.

(B) The facility must also follow the accreditation body's procedures for applying for accreditation of the unit.

(3) Screen-film mammography systems must meet the requirements of 21 CFR Part 900.

(4) [(2)] Motion of tube-image receptor assembly. The x-ray tube must remain physically stable during exposures. In cases where tubes are designed to move during exposure, the facility must ensure proper and free movement of the unit [The assembly shall be capable of being fixed in any position where it is designed to operate.

~~Once fixed in any such position, it shall not undergo unintended motion~~]. In the event of power interruption, this mechanism must [~~shall~~] not fail.

[~~(3) Image receptors. Systems using screen-film image receptors shall, at a minimum, provide for the following:~~]

[~~(A) operation with image receptors of 18 x 24 cm and 24 x 30 cm;~~]

[~~(B) operable moving grids matched to all image receptor sizes provided;~~]

[~~(C) operation with the grid removed from between the source and image receptor for systems used for magnification procedures; and~~]

~~(D) image receptors to rest, post-loading, 15 minutes between exposures.~~]

(5) [~~(4)~~] Magnification. Systems used to perform diagnostic [~~noninterventional problem solving~~] procedures must [~~shall~~] have radiographic magnification capability available for use with[~~, at a minimum,~~] at least one magnification value within the range of 1.4 to 2.0.

(6) [~~(5)~~] Focal spot and target material selection. Selection of the focal spot or target material must [~~shall~~] be as follows.

(A) When more than one focal spot is provided, the system must [~~shall~~] indicate, before [~~prior to~~] exposure, which focal spot is selected.

(B) When more than one target material is provided, the system must [~~shall~~] indicate, before [~~prior to~~] exposure, the preselected target material.

(C) When the target material and [~~and/or~~] focal spot are [~~is~~] selected by a system algorithm [~~that is~~] based on the exposure [~~or on a test exposure~~], after the exposure, the system must [~~shall~~] display[~~, after the exposure,~~] the target material and [~~and/or~~] focal spot [~~actually~~] used during the exposure.

(7) [~~(6)~~] Compression. All mammography systems must [~~shall~~] incorporate a compression device.

(A) Application of compression. Each [~~Effective October 28, 2002, and thereafter, each~~] system must [~~shall~~] provide the following features operable from both sides of the patient:

(i) an initial power-driven compression activated by hands-free controls; and

(ii) fine adjustment compression controls.

(B) Compression paddle.

(i) Systems must [~~shall~~] be equipped with different sized compression paddles matching [~~that match~~] the sizes of all full-field image receptors provided for the system.

(ii) Compression paddles for special purposes, including those smaller than the full size of the image receptor (for example, spot compression) may be provided. Such paddles are not subject to the requirements of clauses (v) and (vi) of this subparagraph.

(iii) Except as provided in clause (iv) of this subparagraph, the compression paddle must [~~shall~~] be flat and parallel to the breast support table and must [~~shall~~] not deflect from parallel by more than 1.0 cm at any point on the surface of the compression paddle when compression is applied.

(iv) Equipment intended by the manufacturer's design to not be flat and parallel to the breast support table during compression must [~~shall~~] meet the manufacturer's design specifications and maintenance requirements.

(v) The chest wall edge of the compression paddle must [~~shall~~] be straight and parallel to the edge of the image receptor.

(vi) The chest wall edge may be bent upward to allow for patient comfort, but must [~~shall~~] not appear on the image.

(8) [~~(7)~~] Technique factor selection and display. Technique factor selection and display must [~~shall~~] be as follows.

(A) Manual selection of milliampere seconds (mAs) or at least one of its component parts, milliampere (mA) or [~~and/or~~] time, must [~~shall~~] be available.

(B) The technique factors (kVp [~~peak tube potential in kilovolts (kV)~~] and either tube current in mA and exposure time in seconds or the product of tube current and exposure time in mAs) [~~to be~~] used during an exposure must [~~shall~~] be indicated before the exposure begins, except when AEC [~~automatic exposure control (AEC)~~] is used, in which case the technique factors that are set before [~~prior to~~] the exposure must [~~shall~~] be indicated.

(C) When the AEC mode is used, the system must [~~shall~~] indicate the actual kVp and mAs used during the exposure. The mAs may be displayed as mA and time.

(9) [~~(8)~~] Automatic exposure control. Each [~~screen-film~~] system must [~~shall~~] provide an AEC mode [~~that is~~] operable in all combinations of equipment configuration provided, for example, [~~contact, magnification, and~~] various image receptor sizes.

(A) The positioning or selection of the detector must [~~shall~~] permit flexibility in the placement of the detector under the target tissue.

(i) The size and available positions of the detector must [~~shall~~] be clearly indicated at the x-ray input surface of the breast compression paddle.

(ii) The selected position of the detector must [~~shall~~] be clearly indicated.

(B) The system must [~~shall~~] provide means to vary the selected optical density from the normal, or zero, [~~(zero)~~] setting.[~~(9) X-ray film. The registrant shall use x-ray film for mammography that has been designated by the film manufacturer as appropriate for mammography.~~]

[~~(10) Intensifying screens. The registrant shall use intensifying screens for mammography that have been designated by the screen manufacturer as appropriate for mammography and shall use film that is matched to the screen's spectral output as specified by the manufacturer.~~]

[~~(11) Film processing solutions. For processing mammography films, the registrant shall use chemical solutions that are capable of developing the films used by the facility in a manner equivalent to the minimum requirements specified by the film manufacturer.~~]

[~~(12) Lighting. The registrant shall make available special lights for film illumination (hot lights) capable of producing light levels greater than that provided by the view box.~~]

[~~(13) Film masking devices. Registrants shall ensure that film masking devices that can limit the illuminated area to a region equal to or smaller than the exposed portion of the film are available to all interpreting physicians interpreting for the facility.~~]

(10) [~~(14)~~] Equipment variances. Facilities [~~Registrants~~] with mammography equipment with [~~that has been issued~~] variances

issued by the FDA as specified in [~~to Title~~] 21[~~,~~] CFR[~~,~~] §§1020.2, 1020.30, 1020.31, or have [~~has had~~] an alternative to [~~for~~] a quality standard for equipment approved by the FDA as required by [~~under the provisions of Title~~] 21[~~,~~] CFR[~~,~~] §900.18, must [~~shall~~] maintain copies of those variances or alternative standards.

(11) Each mammography machine must meet the following technical specifications.

(A) Kilovoltage peak accuracy and reproducibility. At the most used clinical settings of kVp, the coefficient of variation of reproducibility of the kVp must be equal to or less than 0.02. The kVp must be accurate to within plus or minus 5.0 percent of the indicated or selected kVp at the following:

(i) the lowest clinical kVp that can be measured by a kVp test device;

(ii) the most used clinical kVp; and

(iii) the highest available clinical kVp.

(B) Beam quality and half-value layer (HVL). The HVL must meet the specifications of 21 CFR §1020.30(m)(1) for the minimum HVL. These values, extrapolated to the mammographic range, are shown as follows. This test is performed using the clinical kVp on the standard breast. Values not shown in Table I may be determined by linear interpolation or extrapolation.
Figure: 25 TAC §289.230(i)(11)(B)

(C) Breast entrance air kerma and AEC reproducibility. The coefficient of variation for both air kerma and mAs must not exceed 0.05.

(D) Dosimetry. The average glandular dose delivered during a single view or DBT exposure of an FDA-accepted phantom simulating a standard breast must not exceed 3.0 milligray (mGy) (0.3 rad) per exposure.

(E) X-ray field, light field, image receptor, and compression paddle alignment. All systems must meet the following.

(i) Beam-limiting devices that allow the entire chest wall edge of the x-ray field to extend to the chest wall edge of the image receptor must provide means to ensure the x-ray field does not extend beyond any edge of the image receptor by more than 2.0 percent of the SID.

(ii) The light field passing through the x-ray beam limitation device must be aligned with the x-ray field so the total of any misalignment of the edges, along the length or the width of the visually defined field at the plane of the breast support surface, does not exceed 2.0 percent of the SID.

(iii) When tested with the compression paddle placed above the breast support surface at a distance equivalent to standard breast thickness, the chest wall edge of the compression paddle does not extend beyond the edge of the image receptor by greater than 1.0 percent of the SID. The shadow of the vertical edge of the compression paddle must not be visible in the image.

(12) [~~(15)~~] Light fields. For any mammography system with a light beam that passes through the x-ray beam-limiting device, the light must [~~shall~~] provide an average illumination of not less than 160 lux (15 foot candles) at 100 cm or the maximum SID [~~source-image receptor distance (SID)~~], whichever is less.

(j) [~~(t)~~] Medical records and mammography reports.

(1) Contents and terminology. Each facility must [~~registrant shall~~] prepare a written report of the results of each mammographic examination performed. [~~mammography examination that shall include the following information:~~]

(2) The mammographic examination presented for interpretation must be in the original mammographic modality in which it was performed and must not consist of digital images produced through copying or digitizing hardcopy original images.

(3) The mammography report must include the:

(A) patient name [~~of the patient~~] and an additional patient identifier [~~date of birth~~];

(B) [~~date of the~~] examination date;

(C) facility name and location, including the city, state, zip code, and telephone number of the facility;

(D) [~~(C)~~] name and signature of the IP [~~interpreting physician~~] who interpreted the mammogram (electronic signatures are acceptable);

(E) [~~(D)~~] overall final assessment of findings using the final assessment categories as defined in clauses (i) - (vii) [~~subsection (c)~~] of this subparagraph, [~~section,~~] and classified in one of the following categories with the assessment statement, including only the word or phrase within the quotation marks:

(i) "Negative" indicates nothing to comment upon (if the IP is aware of clinical findings of symptoms, despite the negative assessment, these must be documented and addressed);

(ii) "Benign" indicates a normal result, with benign findings present, but no evidence of malignancy (if the IP is aware of clinical findings or symptoms, despite the benign assessment, these must be documented and addressed);

(iii) "Probably Benign" indicates a finding that has a high probability of being benign;

(iv) "Suspicious" indicates a finding without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant;

(v) "Highly suggestive of malignancy" indicates a finding that has a high probability of being malignant;

(vi) "Known biopsy proven malignancy" is reserved for known malignancies being mammographically evaluated for definitive therapy; or

(vii) "Post procedure mammogram for marker placement" indicates a mammogram to confirm the deployment and position of a breast tissue marker; or

(F) in cases where the final assessment category cannot be assigned due to incomplete work-up, the IP must assign one of the following classification statements and reasons why the final assessment cannot be made:

(i) "Incomplete: Need additional imaging evaluation" is reserved for examinations where additional imaging needs to be performed before an assessment category identified in subparagraph (E)(i) - (vii) of this paragraph can be given; or

(ii) "Incomplete: Need prior mammograms for comparison" is reserved for examinations where comparison with prior mammograms should be performed before an assessment category identified in subparagraph (E) of this paragraph can be given; if this assessment category is used, a follow-up report with an assessment category identified in subparagraph (E)(i) - (v) of this paragraph must be issued within 30 calendar days of the initial report whether or not comparison views can be obtained;

(G) overall assessment of breast density, classified in one of the following categories:

(i) "The breasts are almost entirely fatty";

(ii) "There are scattered areas of fibroglandular density";

(iii) "The breasts are heterogeneously dense, which may obscure small masses"; or

(iv) "The breasts are extremely dense, which lowers the sensitivity of mammography"; and

(H) [~~(E)~~] recommendations made to the healthcare provider [~~physician~~] about what additional actions, if any, should be taken. All clinical questions raised by the referring healthcare provider must [~~physician shall~~] be addressed in the report to the extent possible, even if the assessment is negative or benign.

(4) [~~(2)~~] Communication of mammography results to the patient and healthcare [~~health care~~] providers [~~or physicians~~], as applicable. [~~Each registrant shall send reports as soon as possible, but no later than 30 days from the date of the mammography examination, to:~~]

(A) Each facility must send a mammography report to referring healthcare providers, or patients who do not name a healthcare provider to receive the mammography report, the report described in subsection (j)(3) of this section within 30 days of the mammography examination. If the assessment of the mammography report is "Suspicious" or "Highly suggestive of malignancy," the facility must send this report within seven calendar days of the mammography examination. [~~patients advising them of the results of the mammography examination and any further medical needs indicated. The report shall include a summary written in language easily understood by a lay person; and~~]

(B) Each facility must send a mammography report summary, written in plain language, to patients advising them of the results of the mammography examination and any further medical needs within 30 days of the mammography examination. If the assessment of the mammography report is "Suspicious" or "Highly suggestive of malignancy," the facility must send this report summary within seven calendar days of the final interpretation of the mammogram [~~referring physicians, or in the case of self-referral, to the physician indicated by the patient, advising them of the results of the mammography examination, containing the information specified in paragraph (1) of this subsection, and any further medical needs indicated~~].

(5) A summary of the report written in plain language must be provided within 30 days of interpretation and include:

(A) patient name;

(B) name, address, and telephone number of the facility performing the mammographic examination; and

(C) assessment of breast density as described in subsection (j)(3)(G) of this section, as applicable.

(i) If the mammography report identifies the patient's breast density as "The breasts are almost entirely fatty" or "There are scattered areas of fibroglandular density," the summary must include the statement, "Breast tissue can be either dense or not dense. Dense tissue makes it harder to find breast cancer on a mammogram and also raises the risk of developing breast cancer. Your breast tissue is not dense. Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation."

(ii) If the mammography report identifies the breast density as "The breasts are heterogeneously dense, which may obscure small masses" or "The breasts are extremely dense, which lowers the sensitivity of mammography," the summary must include the statement, "Breast tissue can be either dense or not dense. Dense tissue makes it harder to find breast cancer on a mammogram and also raises the risk of developing breast cancer. Your breast tissue is dense. In some people with dense tissue, other imaging tests in addition to a mammogram may help find cancers. Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation."

(6) [~~(3)~~] Follow-up with patients and healthcare provider [~~physicians~~]. Each facility must [~~registrant shall~~] follow-up to confirm if [~~the following~~]:

(A) [~~that~~] patients with positive findings and patients needing repeat examinations [~~exams~~] have received proper notification; and

(B) healthcare providers [~~that physicians~~] have received proper notification of patients with positive findings or needing repeat examinations [~~exams~~].

(7) [~~(4)~~] Retention of clinical images for a current, closed, or terminated facility [~~registrants~~].

(A) A facility must implement policies and procedures to minimize the possibility of loss of these records. The original mammograms must be retained, in retrievable form in the mammographic modality in which they were produced, for a minimum of five years. Original mammograms cannot be produced by copying or digitizing hardcopy originals [~~Each registrant that performs mammograms shall maintain mammography films and reports in a permanent medical record for a minimum of five years~~]. If [~~no~~] additional mammograms of the patient are not performed at the facility, the images [~~films~~] and reports must [~~shall~~] be maintained for a minimum of 10 [~~ten~~] years as specified in subsection (x) of this section.

(B) Each facility performing [~~registrant that performs~~] mammograms must [~~shall~~], within 15 calendar [~~30~~] days of request by or on behalf of the patient, permanently or temporarily transfer the original mammograms and copies of the patient's reports to a medical institution, a physician, or to the patient directly.

(i) Transferred mammograms must be in the mammographic modality in which they were produced and cannot be produced by copying or digitizing hardcopy originals.

(ii) For digital mammograms or DBT, if the examination is being transferred for final interpretation purposes, the facility must be able to provide the recipient with original digital images electronically.

(C) If the medical records are permanently forwarded, the receiving institution or physician must [~~shall~~] maintain and become responsible for the original images [~~film~~] until the fifth or tenth anniversary, as specified in subparagraph (A) of this paragraph.

(D) Any fee charged to a patient for providing the services in subparagraphs (B) - (C) of this paragraph must not exceed the documented costs associated with this service.

(E) [~~(D)~~] Closure [~~Upon closure~~] or termination.[~~,~~]

(i) The facility must [~~the registrant shall~~] maintain the mammography images [~~films~~] for five [~~5~~] years. [~~If the facility complies with the following:~~]

(ii) [~~(i)~~] Within [~~within~~] 180 days of closing, the facility must [~~registrant shall directly~~] notify each patient or patient's representative with instructions on how to access [~~retrieve~~] or authorize disposal of the patient's records.[~~; and~~]

(I) Access may be provided by the permanent transfer of mammographic records to the patient, the patient's healthcare provider, or a facility or other entity that will provide access to patients and healthcare providers. Access to the records must be provided by the facility or other entity for the remainder of the time periods specified in subparagraph (A) of this paragraph.

(II) If a facility ceases to perform mammography but continues to operate as a medical entity and is able to satisfy the record keeping requirements of subparagraph (A) of this paragraph, it may choose to continue to retain the medical records rather than transfer them to another facility, unless a transfer is requested by, or on behalf of, the patient. The facility must notify the AB and department in writing of the arrangements it has made and must make reasonable efforts to notify all affected patients.

(iii) [~~(ii)~~] Within [~~within~~] 60 days of closing, the facility must [~~registrant shall~~] publish a notice in at least one newspaper, or publicly available media, [~~or more newspapers~~] covering the geographical area served by the closing facility. The notice must [~~shall~~] include:

(I) contact information for [~~on~~] retrieving patient records; and

(II) information that the records will be destroyed if not retrieved by the patient or the patient's representative within five [~~5~~] years.[~~; and~~]

(iv) [~~(iii)~~] If [~~if~~] records have not been retrieved by the patient or the patient's representative during [~~following~~] the five-year [~~5-year~~] period after closing, the registrant may destroy the records.

(8) [~~(5)~~] Mammographic image identification. Each mammographic image must include [~~shall have~~] the following information indicated on it in a permanent, legible manner and placed so it does [~~as~~] not [~~to~~] obscure anatomic structures:

(A) patient name [~~name of patient~~] and date of birth;

(B) date of examination;

(C) view and laterality, [~~(this information shall be~~] placed on the image in a position near the axilla[~~)~~];

(D) facility name and location, including [~~(at a minimum the location shall include~~] city, state, and zip code[~~)~~];

(E) MRT [~~technologist~~] identification;

(F) cassette [~~cassette/screen~~] identification, if applicable; [~~and~~]

(G) mammography machine identification, if there is more than one machine in the facility;[~~.~~]

(H) compressed breast thickness or degree of compression; and

(I) kVp.

[~~(6) Information shall also be maintained for each clinical image by utilizing a label on each film, recording on the film jacket, or maintaining a log or other means. The information shall include, but is not limited to, compressed breast thickness or degree of compression, and kVp.~~]

(k) [~~(u)~~] Quality assurance - general. Each facility must [~~registrant shall~~] establish and maintain a written quality assurance program to ensure the safety, reliability, clarity, and accuracy of mammography services performed at the mammography facility, including corrective actions [~~to be~~] taken if images are of poor quality.

(1) Responsible individuals. Responsibility for the QA [~~quality assurance~~] program and [~~for~~] each of its elements must [~~shall~~] be assigned to individuals who are qualified for their assignments and [~~who shall be~~] allowed adequate time to perform these duties.

(A) Lead interpreting physician. The facility must [~~registrant shall~~] identify a LIP [~~lead interpreting physician~~] who is responsible for [~~shall have the general responsibility of~~]:

(i) ensuring [~~that~~] the QA [~~quality assurance~~] program meets all requirements of this subsection and subsections (l) and (m)[~~(v) and (w)~~] of this section;

(ii) reviewing and documenting, with date and signature, the MRTs' QC [~~technologists' quality control~~] test results at least every three months or more frequently if consistency has not yet been achieved;

(iii) reviewing and documenting, with date and signature, the physicists' results within 60 days of the receipt of the results or more frequently when needed; and

(iv) assigning the individual and evaluating their [~~determining the individual's~~] qualifications to perform the QA [~~quality assurance~~] tasks in subparagraphs (B) - (D) of this paragraph.

(B) Interpreting physicians. All [~~interpreting~~] physicians interpreting mammograms for a facility must [~~the registrant shall~~]:

(i) follow the facility's [~~registrant's~~] procedures for corrective action when the images they are asked to interpret are of poor quality; these [~~. These~~] procedures must [~~shall~~] be included in the facility's operating and safety procedures (OSP); and

(ii) participate in the medical outcomes audit program.

(C) Medical physicist. Each facility must [~~registrant shall~~] use the services of a licensed medical physicist to survey mammography equipment and oversee the equipment-related QA [~~quality assurance~~] practices of the facility. At a minimum, the medical physicist is [~~shall be~~] responsible for performing the surveys, performing [~~and the~~] mammography equipment evaluations, and providing the facility with the reports described in subsection (l)(5) and (6)[~~(v)(10) and (11)~~] of this section.

(D) Quality control technologist. The QC [~~quality control~~] technologist, designated by the LIP [~~lead interpreting physician~~], must [~~shall~~] ensure performance of the items designated in subsection (l)(1) - (4), (7), and (9) [~~(v)(1) - (4), (7) - (9), (12), and (14)~~] of this section. If other personnel are assigned the QA [~~quality assurance~~] tasks in accordance with subparagraph (A)(iv) of this paragraph, the QC [~~quality control~~] technologist must ensure [~~shall insure that~~] the requirements of subsection (l)(1) - (4), (7), and (9) [~~(v)(1) - (4), (7) - (9), (12), and (14)~~] of this section are met.

(2) Quality assurance records.

(A) The LIP [~~lead interpreting physician~~], QC [~~quality control~~] technologist, and medical physicist must [~~shall~~] ensure [~~that~~] records concerning mammography technique and procedures, QC [~~quality control~~] (include monitoring data, corrective actions, and the effectiveness of the corrective actions), safety, protection, and employee qualifications related to [~~meet~~] assigned QA [~~quality assurance~~] tasks are properly maintained and updated.

(B) The QC [~~These quality control~~] records must [~~shall~~] be kept for each test specified in subsections (l) and (m)[~~(v) and (w)~~] of this section, as specified in [~~accordance with~~] subsection (x)[~~(ee)~~] of this section.

(l) [~~(v)~~] Quality assurance - equipment. [~~Registrants with screen-film systems shall perform the following quality control tests at the intervals specified. In addition to the intervals specified in paragraphs (4)(B) and (5)(H) of this subsection, the tests shall be performed prior to initial use.~~]

(1) Facilities with screen-film systems must perform QC tests as specified in 21 CFR Part 900 [~~Daily quality control tests. Film processors used to develop mammograms shall be adjusted and maintained to meet the technical development specifications for the mammography film in use. A processor performance test shall be completed and the results charted on each day that clinical films are processed before any clinical films are processed that day~~].

[~~(A) Processor performance test. Using mammography film used clinically at the facility, sensitometer tests shall include assessment of the following:~~]

~~*(i)* base plus fog density that shall be within plus 0.03 of the established operating level;~~]

~~*(ii)* mid-density that shall be within plus or minus 0.15 of the established operating level; and~~]

~~*(iii)* density difference that shall be within plus or minus 0.15 of the established operating level.~~]

[~~(B) Film processors being used for mammography at multiple locations, such as a mobile service operation, shall be subject to the requirements of this paragraph.~~]

[~~(C) Film processors utilized for mammography shall be adjusted to and operated at the specifications recommended by the mammographic film manufacturer, or at other settings such that the sensitometric performance is at least equivalent.~~]

[~~(D) Each registrant shall utilize the same film processor for clinical and phantom images. Clinical images shall be processed within an interval not to exceed 24 hours from the time the first clinical image is taken. Facilities utilizing batch processing shall do the following:~~]

~~*(i)* use a container to transport clinical images that will protect the film from exposure to light and radiation; and~~]

~~*(ii)* maintain a log to include each patient name and unique identification number, date, and time of the first exam of each batch, and date and time of batch development.~~]

(2) Systems with image receptor modalities, other than screen-film, must follow a QA program that is substantially the same as the one recommended by the image receptor manufacturer [~~Weekly quality control tests. These tests shall be performed at an interval no greater than seven days. If mammography is not being performed on the date the test is due and more than seven days have past since the last test, the tests shall be performed prior to resuming mammography. An image quality evaluation test, using an FDA-accepted phantom, shall meet the following parameters~~].

[~~(A) The optical density of the film at the center of an image of a standard FDA-accepted phantom shall be at least 1.20 when exposed under a typical clinical condition and shall not change by more than plus or minus 0.20 from the established operating level.~~]

[~~(B) The density difference between the background of the phantom and an added test object, used to assess image contrast, shall be measured and shall not vary by more than plus or minus 0.05 from the established operating level.~~]

[~~(C) The phantom image shall be made on the standard mammographic film in use at the facility with techniques used for clinical images of a standard breast. The phantom image shall meet the requirements in subparagraphs (A) and (B) of this paragraph and clause (i) of this subparagraph. No mammograms shall be taken on patients if any of these minimums are not met.~~]

~~*(i)* The mammographic machine shall be capable of producing images of the mammographic phantom in accordance with the phantom image scoring protocol in subsection (hh)(4) of this section or paragraph (7) of this subsection.~~]

~~*(ii)* Each phantom image and a record of the evaluation of that image shall be maintained at the location where the mammography image was produced or with the radiographic equipment for mobile service operations.~~]

[~~(3) Quarterly quality control tests. These tests shall be performed within the calender quarter at an interval not to exceed 90 days.~~]

[~~(A) Fixer retention in film. The residual fixer shall be no more than 5 micrograms per square cm.~~]

[~~(B) Repeat analysis. A repeat analysis on clinical images repeated or rejected shall be performed, analyzed, and documented. The total repeat or reject rate shall not exceed 5.0%. If the total repeat or reject rate changes from the previously determined rate by more than 2.0% of the total films included in the analysis, the reason(s) for the change shall be determined. Corrective action shall be taken and documented if the total repeat or reject rate for the facility exceeds 5.0% or changes from the previously determined rate by more than 2.0% of the total films included in the analysis. Test films, cleared films, or film processed as a result of exposure of a film bin are not to be included in the count for repeat analysis. Films included in the repeat analysis are not required to be kept after completion of the analysis.~~]

[~~(4) Semiannual quality control tests. These tests shall be performed at an interval not to exceed six months.~~]

[~~(A) Darkroom fog. The optical density attributable to darkroom fog shall not exceed 0.05 when a mammography film of the type used in the facility, which has a mid-density of no less than 1.2 OD, is exposed to typical darkroom conditions for two minutes while such film is placed on the counter top, emulsion side up. If the darkroom has a safelight used for mammography film, it shall be on during this test.~~]

[~~(B) Screen-film contact. Testing for screen-film contact shall be conducted using 40 mesh copper screen. The entire area of the cassette that may be clinically exposed shall be tested. This shall include all cassettes used for mammography in the facility.~~]

[~~(C) Compression device performance. The maximum compression force for the initial power drive shall be between 25 pounds and 45 pounds. The system shall be capable of compressing the breast with a force of at least 25 pounds and shall be capable of maintaining this compression for at least 15 seconds.~~]

[~~(5) Annual quality control tests. These tests shall be performed at an interval not to exceed (14) months.~~]

[~~(A) Automatic exposure control performance. The AEC shall be capable of maintaining film optical density within plus or minus 0.15 of the mean optical density when thickness of a homogeneous material is varied over a range of 2 to 6 cm and the kVp is varied appropriately for such thicknesses over the kVp range and in the AEC mode used clinically in the facility.~~]

[~~(B) Kilovoltage peak accuracy and reproducibility. At the most commonly used clinical settings of kVp, the coefficient of variation of reproducibility of the kVp shall be equal to or less than~~

0.02. The kVp shall be accurate to within plus or minus 5.0% of the indicated or selected kVp at the following:]

[(i) the lowest clinical kVp that can be measured by a kVp test device;]

(ii) the most commonly used clinical kVp; and]

(iii) the highest available clinical kVp.]

[(C) Focal spot condition. Facilities shall evaluate focal spot condition by determining the system resolution as follows.]

[(i) Each system used for mammography, in combination with the mammography screen-film combination used in the facility, shall provide a minimum resolution of 11 cycles/millimeter (mm) (line-pairs/mm) when a high contrast resolution bar test pattern is oriented with the bars perpendicular to the anode-cathode axis, and a minimum resolution of 13 line-pairs/mm when the bars are parallel to that axis.]

[(ii) The bar pattern shall be placed 4.5 cm above the breast support surface, centered with respect to the chest wall edge of the image receptor, and with the edge of the pattern within 1 cm of the chest wall edge of the image receptor.]

[(iii) When more than one target material is provided, the measurement in clause (i) of this subparagraph shall be made using the appropriate focal spot for each target material.]

[(iv) When more than one SID is provided, the test shall be performed at the SID most commonly used clinically.]

[(v) Test kVp shall be set at the value used clinically by the facility for a standard breast and shall be performed in the AEC mode, if available. If necessary, a suitable absorber may be placed in the beam to increase exposure times. The screen-film cassette combination used by the facility shall be used to test for this requirement and shall be placed in the normal location used for clinical procedures.]

[(D) Beam quality and half-value layer (HVL). The HVL shall meet the specifications of Title 21, CFR, §1020.30(m)(1) for the minimum HVL. These values, extrapolated to the mammographic range, are shown as follows. This test is performed using the clinical kVp on the standard breast. Values not shown in Table I may be determined by linear interpolation or extrapolation.]
[Figure: 25 TAC §289.230(v)(5)(D)]

[(E) Breast entrance air kerma and AEC reproducibility. The coefficient of variation for both air kerma and mAs shall not exceed 0.05.]

[(F) Dosimetry. The average glandular dose delivered during a single craniocaudal view of an FDA accepted phantom simulating a standard breast shall not exceed 3.0 milligray (mGy) (0.3 rad) per exposure.]

[(G) X-ray field/light field/image receptor/compression paddle alignment. All systems shall meet the following.]

[(i) All systems shall have beam-limiting devices that allow the entire chest wall edge of the x-ray field to extend to the chest wall edge of the image receptor and provide means to assure that the x-ray field does not extend beyond any edge of the image receptor by more than 2.0% of the SID.]

[(ii) If a light field that passes through the x-ray beam limitation device is provided, it shall be aligned with the x-ray field so that the total of any misalignment of the edges of the light field and the x-ray field along either the length or the width of the visually defined field at the plane of the breast support surface shall not exceed 2.0% of the SID.]

[(iii) The chest wall edge of the compression paddle shall not extend beyond the chest wall edge of the image receptor by more than 1.0% of the SID when tested with the compression paddle placed above the breast support surface at a distance equivalent to standard breast thickness. The shadow of the vertical edge of the compression paddle shall not be visible on the image.]

[(H) Uniformity of screen speed. Uniformity of screen speed of all the cassettes in the facility shall be tested and the difference between the maximum and minimum optical densities shall not exceed 0.30. Screen artifacts shall also be evaluated during this test.]

[(I) System artifacts. System artifacts shall be evaluated with a high-grade, defect-free sheet of homogeneous material large enough to cover the mammography cassette and shall be performed for all cassette sizes used in the facility using a grid appropriate for the cassette size being tested. System artifacts shall also be evaluated for all available focal spot sizes and target filter combinations used clinically.]

[(J) Radiation output. The system shall be capable of producing a minimum output of 7.0 mGy air kerma per second (800 milliroentgen (mR) per second) when operating at 28 kVp in the standard mammography mode at any SID where the system is designed to operate. The system shall be capable of maintaining the required minimum radiation output averaged over a 3.0 second period.]

[(K) Decompression. If the system is equipped with a provision for automatic decompression after completion of an exposure or interruption of power to the system, the system shall be tested to confirm that it provides the following:]

[(i) an override capability to allow maintenance of compression;]

[(ii) a continuous display of the override status; and]

[(iii) a manual emergency compression release that can be activated in the event of power or automatic release failure.]

[(L) The technique settings used for subparagraph (F) of this paragraph and paragraph (2) of this subsection shall be those used by the facility for its clinical images of a standard breast.]

[(6) Densitometer and sensitometer. The calibration of the densitometer and sensitometer must be in accordance with the manufacturer's specifications.]

[(7) Quality control tests - other modalities. For systems with image receptor modalities other than screen-film, the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems in paragraph (5)(F) of this subsection.]

(3) [(8)] Mobile service operation.

(A) The mobile facility must [registrant shall] verify [that] mammography machines used to produce mammograms at more than one location meet the requirements in paragraphs (1) and (2) [(1) - (7)] of this subsection.

(B) At [In addition, at] each examination location, before any examinations are conducted, the facility must [registrant shall] verify satisfactory performance of the mammography machines by using a testing [test] method, as required by the manufacturer, establishing [that establishes] the adequacy of the image quality produced by the machine.

(C) Processor performance testing must be completed as required by 21 CFR Part 900 [shall be in accordance with paragraph (1) of this subsection].

(4) [~~(9)~~] Use of test results. After completion of the tests specified in paragraphs (1) and (2) [~~(1)~~ - ~~(8)~~] of this subsection, the following must [~~shall~~] occur.

(A) The facility must [~~registrant shall~~] compare the test results to the [~~corresponding specified action limits; or, for nonscreen-film modalities, to the~~] manufacturer's recommended action limits[~~; or for post-move, pre-examination testing of mobile mammography machines, to the limits established in the test method used by the facility~~].

(B) If components [~~Components~~] of the mammography system [~~that~~] fail QA [~~quality assurance~~] tests, the facility must follow [~~shall have~~] corrective actions required by 21 CFR Part 900, or the QA program recommended by the image receptor manufacturer [~~as indicated in the following~~].

~~*[(i) If components in subclause (I) and (II) of this clause fail, corrective action shall be taken before any mammography films are processed:]*~~

~~*[(I) paragraph (1) of this subsection describing processor quality control; and]*~~

~~*[(II) paragraph (4)(A) of this subsection describing darkroom fog;]*~~

~~*[(ii) If components in subclause (I) - (VI) of this clause fail, corrective action shall be taken before any mammography examinations are performed:]*~~

~~*[(I) paragraph (2) of this subsection describing phantom image quality;]*~~

~~*[(II) paragraph (4)(B) of this subsection describing screen-film contact;]*~~

~~*[(III) paragraph (4)(C) of this subsection describing compression device performance;]*~~

~~*[(IV) paragraph (5)(F) of this subsection describing dosimetry;]*~~

~~*[(V) paragraph (7) of this subsection describing quality control tests of other modalities; and]*~~

~~*[(VI) paragraph (8) of this subsection describing quality control tests for mobile mammography machines.]*~~

~~*[(iii) If components in the remaining quality assurance tests in subsection (v) of this section fail, corrective action shall be taken within 30 days of the test date.]*~~

(C) Documentation of the tests and the corrective actions described in subparagraph (B) of this paragraph must [~~shall~~] be maintained as specified in [~~accordance with~~] subsection (x) [~~(ee)~~] of this section.

(5) [~~(10)~~] Surveys. Annually, not to exceed 14 months from the date of the previous survey [~~At least once a year~~], each mammography system must [~~facility shall~~] undergo a survey by a medical physicist, or [~~by~~] an individual under the direct supervision of a medical physicist, as specified in paragraphs (1) - (3) of this subsection.

~~[(A) At a minimum, this survey shall include the following:]~~

~~*[(i) performance of tests to ensure that the facility meets the quality assurance requirements of the weekly phantom image quality test described in paragraph (2) of this subsection, the annual tests described in paragraph (5) of this subsection, and if applicable, quality control tests as described for other modalities in paragraph (7) and for mobile service operations as described in paragraph (8) of this subsection; and]*~~

~~*[(ii) evaluation of the adequacy of the results of all tests conducted by the facility as well as written documentation of any corrective actions taken and their results in accordance with paragraphs (1) - (4) of this subsection, and, if applicable, paragraphs (7) and (8) of this subsection.]*~~

(A) [~~(B)~~] The medical physicist must [~~shall~~] provide a written survey report to the facility within 30 days of the date of the survey. The report must [~~shall~~] include a summary of the test performed, all test conditions, specifications, results, and recommendations for corrective actions[~~, in accordance with subparagraph (A)(i) and (ii) of this paragraph~~].

(B) [~~(C)~~] If any deficiencies require immediate corrective action as specified in paragraphs (1) - (3) of this subsection [~~the following tests indicate deficiencies~~], the physicist must [~~shall~~] give a preliminary [~~oral or~~] written report to the facility within 72 hours of the survey.[~~:~~]

~~*[(i) processor quality control in accordance with paragraph (9)(B)(i)(I) of this subsection;]*~~

~~*[(ii) phantom images, screen-film contact, compression device performance, or dosimetry in accordance with paragraph (9)(B)(ii)(I) - (IV) of this subsection;]*~~

~~*[(iii) quality control tests for other modalities, if applicable, in accordance with paragraph (9)(B)(ii)(V) of this subsection; or]*~~

~~*[(iv) quality control tests for mobile mammography machines, if applicable, in accordance with paragraph (9)(B)(ii)(VI) of this subsection.]*~~

(C) [~~(D)~~] The survey report must include the: [~~shall be dated and signed by the medical physicist performing or supervising the survey. If the survey was performed entirely or in part by another individual under the direct supervision of the medical physicist, that individual and the part of the survey that individual performed shall also be identified in the survey.~~]

(i) date, name, and signature of the medical physicist performing or supervising the survey;

(ii) name and signature of each individual under the direct supervision of the medical physicist performing any part of the survey, as applicable;

(iii) name of the facility;

(iv) address of facility;

(v) registration number of the facility;

(vi) make, model, and serial number from the machine control panel;

(vii) registration number of the service provider performing the survey;

(viii) service provider email address;

(ix) business mailing address of the service provider performing the survey; and

(x) date of the last calibration of testing equipment.

(D) [~~(E)~~] The facility must maintain the survey report as specified [~~shall be maintained by the registrant~~] in [~~accordance with~~] subsection (x)[~~(ee)~~] of this section.

(6) [~~(11)~~] Mammography equipment evaluations. Additional evaluations of mammography machines must follow manufacturer specifications. Screen-film mammography machines must follow applicable requirements in 21 CFR Part 900. The mammography equipment evaluation and dosimetry must be performed by a medical physicist or an individual under the direct supervision of a medical physicist [~~or image processors shall be conducted whenever a new mammography machine or processor is installed, a mammography machine or processor is disassembled and reassembled at the same or a new location, major components of mammography machine are changed or repaired, or a processor is overhauled or reconditioned. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in this subsection and subsection (s) of this section~~].

[~~(A) All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing.~~]

[~~(B) The mammography equipment evaluation and dosimetry shall be performed by a medical physicist or by an individual under the direct supervision of a medical physicist.~~]

(7) Each diagnostic review workstation (RWS) used to interpret images must follow manufacturer specifications for display conditions and quality control. If the RWS manufacturer does not specify QC procedures, then a QA program that is substantially the same as the QA program recommended by the image receptor manufacturer must be established and followed.

[~~(12) Facility cleanliness. The registrant shall establish and implement adequate protocols for maintaining darkroom, screen, and view box cleanliness and shall document that all cleaning procedures are performed at the frequencies specified in the protocols.~~]

(8) [~~(13)~~] Calibration of air kerma measuring instruments. Instruments used by medical physicists in their annual survey and mammography equipment evaluation to measure the air kerma or air kerma rate from a mammography machine must [~~shall~~] be calibrated at least once every two years and each time the instrument is repaired. The instrument calibration must be traceable to a national standard and calibrated with an accuracy of plus or minus six percent, or 95 percent confidence level, [~~6.0% (95% confidence level)~~] in the mammography energy range.

(9) [~~(14)~~] Infection control. Facilities must [~~shall~~] establish and comply with a system specifying procedures [~~to be followed by the facility~~] for cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials. This system must [~~shall~~] specify the methods for documenting facility compliance with the infection control procedures established and must [~~shall~~]:

(A) comply with all applicable federal, state, and local regulations pertaining to infection control; and

(B) comply with the manufacturer's recommended procedures for the cleaning and disinfection of the mammography equipment used in the facility; or

(C) if adequate manufacturer's recommendations are not available, comply with generally accepted guidance on infection control, until such recommendations become available.

(m) [~~(w)~~] Quality assurance - mammography medical outcomes audit. Each registrant must [~~shall~~] establish and maintain a mammography medical outcomes audit program to followup [~~follow-up~~] positive mammographic assessments and to correlate pathology results with the IP's [~~interpreting physician's~~] findings. The [~~This~~] program must [~~shall~~] be designed to ensure the reliability, clarity, and accuracy of the interpretation of mammograms.

(1) General requirements.

(A) Each facility must [~~registrant shall~~] establish a system to collect and review outcome data for all mammograms performed, including follow-up on the disposition of all positive mammograms and correlation of pathology results with the IP's [~~interpreting physician's~~] mammography report.

(B) For cases of breast cancer among patients imaged at the facility that become known to the facility, the facility must initiate a follow-up on surgical and pathology results and a review of the mammographic examinations taken before the diagnosis of a malignancy.

(C) The [~~Analysis of these~~] outcome data must [~~shall~~] be made individually and collectively for all IPs [~~interpreting physicians~~] at the facility and include determinations of the following. [~~In addition, any cases of breast cancer among women imaged at the facility that subsequently become known to the facility shall prompt the facility to initiate follow-up on surgical and/or pathology results and review of the mammograms taken prior to the diagnosis of a malignancy.~~]

(i) Positive predictive value. The percent of patients with positive mammograms who are diagnosed with breast cancer within one year of the date of the mammographic examination.

(ii) Cancer detection rate. Of the patients initially examined with screening mammograms who receive an assessment of "Incomplete: Need additional imaging evaluation," "Suspicious," or "Highly Suggestive of Malignancy" on the screening mammogram or on a subsequent diagnostic mammogram, the number of patients who are diagnosed with breast cancer within one year of the date of the initial screening mammogram, expressed as a ratio per 1,000 patients.

(iii) Recall rate. The percentage of screening mammograms given an assessment of "Incomplete: Need additional imaging evaluation."

(2) Frequency of audit analysis. The facility's first audit analysis must begin within [~~shall be initiated no later than~~] 12 months of the facility becoming certified, and completed within the following 12 months [~~after the date the facility becomes certified or 12 months after April 28, 1999, whichever date is the latest. This audit analysis shall be complete within an additional 12 months~~] to permit completion of diagnostic procedures and data collection.

(A) Subsequent audit analyses will be conducted at least once every 12 months.

(B) The facility must maintain the audit analysis as specified in [~~These shall be maintained in accordance with~~] subsection (x)[~~(ee)~~] of this section.

(3) Reviewing interpreting physician. Each LIP [~~lead interpreting physician~~] or an interpreting physician designated by the LIP must [~~lead interpreting physician shall~~] review the medical outcomes audit data at least annually, not to exceed [~~once every~~] 12 months following the data collection period. This individual must [~~shall~~] analyze the results of the audit and is [~~shall be~~] responsible for the following:

(A) recording the dates of the audit period [~~period(s)~~];

(B) documenting the results;

(C) notifying other IPs [~~interpreting physicians~~] of their results and the facility's collective [~~registrant's aggregate~~] results; [~~and~~]

(D) documenting any follow up actions and the nature of the follow up; and[.]

(E) recording the audit completion by providing a signature and date on the audit.

(n) [(x)] Mammographic procedure and techniques for mammography of patients with breast implants. Each registrant must [shall] have a procedure to inquire if [whether or not] the patient has breast implants before [prior to] the mammographic exam. Except where contraindicated, or unless modified by a physician's directions, patients with breast implants must [shall] have mammographic views to maximize the visualization of breast tissue.

(o) [(y)] Complaints. Each accredited facility must [shall] do the following:

(1) establish a written procedure for collecting and resolving consumer complaints;

(2) maintain a record of each serious complaint received by the facility as specified in [accordance with] subsection (x) [(ee)] of this section; [and]

(3) provide the consumer with adequate directions for filing serious complaints with the facility's AB if the facility is unable to resolve a serious complaint to the consumer's satisfaction; and

(4) [(3)] report unresolved serious complaints to the facility's AB [FDA-approved accreditation body] within 30 days of receiving the complaint.

(p) [(z)] Clinical image quality. Clinical images produced by any certified facility must continue to comply with the standards for clinical image quality established by the [that] facility's AB [accreditation body].

(q) [(aa)] Additional mammography review, targeted clinical reviews, and patient notification.

(1) If the department [agency certifying body] believes the [that] mammography quality at a facility is [may have been] compromised and presents a serious risk to human health, the facility must [shall] provide clinical images and other relevant information, as specified by the department [agency certifying body], for review by the AB [FDA-approved accreditation body]. The additional mammography review will assist the department with determining:

(A) the facility's compliance with this section; and

(B) if there is a need to notify affected patients, their healthcare provider, or the public that the reliability, clarity, and accuracy of the interpretation of mammograms has been compromised.

(2) If the department [agency certifying body] determines the [that] mammography quality at a facility has been compromised and presents a serious risk to human health, the facility must [shall] provide clinical images and other relevant information, as specified by the department [agency certifying body], for review by the AB [FDA-approved accreditation body]. The department [agency certifying body] may require such facility to notify patients who received mammograms[,] and their referring healthcare provider [physicians]. The notification must occur within a time frame and in a manner specified by the department. The notification must: [shall include the deficiencies presenting such risk, the potential consequences to the patient, appropriate remedial measures, and such other relevant information as the agency certifying body may require. Such notification shall occur within a time frame and in a manner specified by the agency.]

(A) inform the patient the mammography system failed to satisfy the department and AB's standards;

(B) recommend the patient consult with the patient's healthcare provider regarding the need for another mammogram;

(C) list three non-affiliated facilities closest to the original testing facility that have a certified mammography system; and

(D) include the deficiencies presenting such risk, the potential consequences to the patient, appropriate remedial measures, and other relevant information required by the department.

(3) If the facility is unable or unwilling to perform such notification, the department may notify patients and their referring physicians or other healthcare providers individually or through the mass media.

(4) [(3)] The department, the AB [agency certifying body, the agency accreditation body or another FDA-approved accreditation body], or the FDA may request a targeted clinical image review [due to, but not limited to, serious complaints or severe items of non-compliance].

(r) [(bb)] Self-referral mammography. Any person proposing to conduct a self-referral mammography program must [shall] not initiate such a program without prior approval from [of] the department [agency]. When requesting such approval, the [that] person must [shall] submit the following information:

(1) the number and type of views (or projections);

(2) the age of the population to be examined and the frequency of the exam following established, nationally recognized criteria, such as those of the American Cancer Society, American College of Radiology (ACR), or the National Council on Radiation Protection and Measurements;

(3) written procedures to include methods of:

(A) advising a patient [patients] and healthcare provider [private physicians] of the results of the mammography examination as specified in [accordance with] subsection (j)(4) [(t)(2)] of this section;

(B) follow-up with patients and healthcare provider as specified [physicians] in [accordance with] subsection (j)(6) [(t)(3)] of this section; and

(C) recommending a healthcare provider to patients who do not have a healthcare provider when clinically indicated, to include when a patient's mammogram assessment is probably benign, suspicious, or highly suggestive of malignancy [physician means of selecting a physician]; and

(4) methods for educating mammography patients in breast self-examination techniques and on the necessity for follow-up by a physician.

(s) [(cc)] Medical research and investigational devices.

(1) Any research using radiation producing devices on humans must be approved by an IRB as required by [Title] 45[,] CFR[,] Part 46 and [Title] 21[,] CFR[,] Part 56. The IRB must include at least one licensed physician to direct any use of radiation as specified in [accordance with] §289.231(b) of this subchapter [title].

(2) Facilities with mammography machines with investigational device exemptions [that are] involved in clinical studies must comply with primary regulations governing [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 [the following]:

[(A) 21 CFR, Part 812, Investigational Device Exemptions;]

(A) [~~(B)~~] 21 CFR[~~,~~] Part 50, Protection of Human Subjects;[~~(C) 21 CFR, Part 56, Institutional Review Boards;~~]

(B) [~~(D)~~] 21 CFR[~~,~~] Part 54, Financial Disclosure by Clinical Investigators;

(C) 21 CFR Part 56, Institutional Review Boards;

(D) 21 CFR Part 812, Investigational Device Exemptions; and

(E) 21 CFR[~~,~~] Part 820 [~~821~~], Subpart C, Design Controls [~~of the Quality System Regulation~~].

(t) [~~(dd)~~] Operating and safety [~~Other operating~~] procedures (OSP).

(1) Each facility must implement and maintain written OSP [~~Operating and safety procedures. Each registrant shall have and implement written operating and safety procedures that shall be made available to each individual operating x-ray equipment, including any restrictions of the operating technique required for the safe operation of the particular system. These procedures shall include, but are not limited to, the items in subsection (hh)(3) of this section~~].

(2) The OSP must be available to each individual operating x-ray equipment, including any restrictions of the operating technique required for the safe operation of the particular system.

(3) The facility's OSP must address the following requirements, as applicable:

(A) §289.203(b) of this chapter, related to posting notices to workers;

(B) §289.203(c) of this chapter, related to instructions to workers;

(C) §289.203(d) of this chapter, related to notifications and reports to individuals;

(D) §289.231(b) of this subchapter, related to ordering x-ray examinations;

(E) §289.231(m) of this subchapter, related to occupational dose requirements;

(F) §289.231(n) and (q) of this subchapter, related to personnel monitoring requirements;

(G) §289.231(x) and (y) of this subchapter, related to posting of a radiation area;

(H) subsection (h) of this section, related to credentialing requirements for LIPs, IPs, MRTs, and medical physicists;

(I) subsection (j)(7) of this section, related to retention of clinical images;

(J) subsections (k) - (m) of this section, related to quality assurance program;

(K) subsection (k)(1)(B)(i) of this section, related to image quality and corrective action for images of poor quality;

(L) subsection (l)(1) - (3) of this section, related to repeat analysis;

(M) subsection (n) of this section, related to procedures and techniques for mammography patients with breast implants;

(N) subsection (o) of this section, related to the procedure to handle complaints;

(O) subsection (r) of this section, related to self-referral mammography;

(P) subsection (u)(2) of this section, related to the use of a technique chart;

(Q) subsection (u)(5) of this section, related to exposure of individuals other than the patient;

(R) subsection (u)(6) of this section, related to use of protective devices; and

(S) subsection (u)(7) of this section, related to holding of patients or image receptors.

(u) Other operating procedures.

(1) Phantom image scoring protocol must be performed as specified in (l)(1) - (3) of this section.

(2) Technique chart. A technique chart or manual must [~~shall~~] be provided and followed. It must be [~~or electronically~~] displayed in the vicinity of the control panel of each machine that specifies technique factors used for a [~~to be utilized versus~~] patient's anatomical size. [~~The technique chart shall be used by all operators.~~]

(3) Receipt, transfer, and disposal of mammography machines. Each registrant must [~~shall~~] maintain records showing the receipt, transfer, and disposal of mammographic machines. These records must [~~shall~~] include the date of receipt, transfer, and [~~or~~] disposal; the name and signature of the person [~~individual~~] making the record; and the manufacturer's model name and serial number from the control panel of the mammographic machine. Records must [~~shall~~] be maintained as specified in [~~accordance with~~] subsection (x)[~~(ee)~~] of this section for inspection by the department [~~agency~~].

(4) Viewing system. Windows, mirrors, closed circuit television, or an equivalent system must [~~shall~~] be provided to permit the operator to continuously observe the patient during irradiation. The operator must [~~shall~~] be able to maintain verbal, visual, and aural contact with the patient.

(5) Exposure of an individual [~~individuals~~] other than the patient. Only the staff and ancillary personnel required for the medical procedure or training may [~~shall~~] be in the room during the radiation exposure unless such individual's assistance is required.

(6) Protective devices. Protective devices must [~~shall~~] be utilized when required, as in paragraph (7) of this subsection.

(A) Protective devices must [~~shall~~] be of no less than 0.25 millimeter (mm) lead equivalent material.

(B) Protective devices, including aprons, gloves, and shields must [~~shall~~] be checked annually for defects such as holes, cracks, and tears. These checks may be performed by the registrant by visual or tactile means, or x-ray imaging. If a defect is found, protective devices must [~~shall~~] be replaced or removed from service until repaired. A record of this test must [~~shall~~] be made and maintained by the registrant as specified in [~~accordance with~~] subsection (x)[~~(ee)~~] of this section for inspection by the department [~~agency~~].

(7) Holding of patient or image receptor.

(A) When a patient or image receptor must be held in position during radiography, mechanical supporting or restraining devices must [~~shall~~] be used when the exam permits.

(B) If a patient or image receptor must be held by an individual during an exposure, the [~~that~~] individual must [~~shall~~] be protected with appropriate shielding devices described in paragraph (6) of this subsection.

(C) The facility's [registrant's] written OSP specified in subsection (t) [operating and safety procedures required by paragraph (1)] of this section must [subsection shall] include the following:

(i) a list of circumstances in which mechanical holding devices cannot be routinely utilized; and

(ii) a procedure used for selecting an individual to hold or support the patient or image receptor.

(D) In those cases where the patient must hold the image receptor, any portion of the body other than the area of clinical interest struck by the useful beam must [shall] be protected by not less than 0.25 mm lead equivalent material.

(8) Calibration, maintenance, and modifications. Each registrant must [shall] maintain records showing calibrations, maintenance, and modifications performed on each mammographic machine. These records must [shall] include the date of the calibration, maintenance, or modification performed; the name of the individual making the record; and the manufacture's model name and serial number of the control panel of the mammographic machine. These records must [shall] be maintained as specified in [accordance with] subsection (x) [(ee)] of this section.

[(ee) Record requirements. Records required by this section shall be maintained for inspection by the agency in accordance with paragraph (3) of this subsection. Records may be maintained electronically in accordance with §289.231(ff)(3) of this title.]

[(1) Records for mammography machines authorized for mobile service operations.]

[(A) Copies of the following shall be kept with mammography machines authorized for mobile services:]

[(i) operating and safety procedures in accordance with subsection (dd)(1) of this section;]

[(ii) medical radiologic technologists' credentials;]

[(iii) current quality control records for at least the last 90 calendar days for on-board processors in accordance with subsection (v)(1) of this section;]

[(iv) current §289.203 of this title, §289.226 of this title, §289.230 of this title, §289.231 of this title, and §289.234 of this title if accredited by the agency accreditation body;]

[(v) copy of certification;]

[(vi) certification of inspection in accordance with subsection (ff)(5) of this section;]

[(vii) notice of failure from last inspection in accordance with subsection (ff)(6) of this section, if applicable; and]

[(viii) copy of mammography accreditation.]

[(B) Copies of all other records required by this section shall be maintained at a specified location.]

[(2) Records required at separate authorized use locations. Copies of the following shall be kept at each separate authorized use location:]

[(A) credentials for interpreting physicians operating at that location in accordance with subsection (r)(1) of this section;]

[(B) credentials for medical radiologic technologists operating at that location in accordance with subsection (r)(2) of this section;]

[(C) credentials for medical physicists operating at that location in accordance with subsection (r)(3) of this section;]

[(D) continuing education and experience records for interpreting physicians, medical radiologic technologists, and medical physicists operating at that location in accordance with subsection (r)(1)(C), (2)(C), and (3)(C) of this section;]

[(E) mandatory training records for interpreting physicians and medical physicists operating at that location in accordance with subsection (r)(1)(E) and (2)(E) of this section, if applicable;]

[(F) current physicist annual survey of the mammography system;]

[(G) current §289.203 of this title, §289.226 of this title, §289.230 of this title, §289.231 of this title, and §289.234 of this title if accredited by the agency accreditation body;]

[(H) copy of certification;]

[(I) quality assurance program in accordance with subsections (u), (v), and (w) of this section;]

[(J) quality control records in accordance with subsection (u)(2) of this section;]

[(K) operating and safety procedures in accordance with subsection (dd)(1) of this section;]

[(L) records of receipts, transfers, and disposal in accordance with subsection (dd)(3) of this section;]

[(M) calibration, maintenance, and modification records in accordance with subsection (dd)(8) of this section;]

[(N) certification of inspection in accordance with subsection (ff)(5) of this section;]

[(O) notification of failure in accordance with subsection (ff)(6), if applicable;]

[(P) records of notification of patients in accordance with subsection (ff)(10) this section; and]

[(Q) copy of mammography accreditation.]

(v) [(ff)] Inspections. In addition to the requirements of §289.231(kk) of this subchapter [title], the following applies to inspections of mammography systems.

(1) The department [agency] may inspect each mammography system that receives a certification as specified in [accordance with] this chapter no [not] later than the 60th day after the date the certification is issued.

(2) The department [agency] may inspect, at least once annually, each mammography system that receives a certification.

(3) To protect the public health, the department [agency] may conduct more frequent inspections than required by this subsection.

(4) The department [agency] may make reasonable attempts to coordinate inspections in this section with other inspections required as specified in [accordance with] this chapter for the facility where the mammography system is used.

(5) After each satisfactory inspection, the department issues [agency shall issue] a certificate of inspection for each mammography system inspected. The certificate of inspection must [shall] be posted at a conspicuous place on or near the place where the mammography system is used. The certificate of inspection includes [may include] the [following]:

(A) specific identification of the mammography system inspected;

(B) [the] name and address of the facility where the mammography system was used at the time of the inspection; and

(C) [the] date of the inspection.

(6) Any severity level I violation involving a mammography system, determined [found] by the department [agency], as specified in [accordance with] §289.205 of this chapter [title], constitutes grounds for posting notice of failure of the mammography system to satisfy department [agency] requirements.

(A) Notification of such failure must [shall] be posted:

(i) on the mammography machine at a conspicuous place if the violation is machine-related; or

(ii) near the place where the mammography system practices if the violation is personnel-related; and

(iii) in a sufficient number of places to permit the patient to observe the notice.

(B) The notice of failure must [shall] remain posted until the facility is authorized to remove it by the department [agency]. A facility may post documentation of corrections of the violations submitted to the department [agency] along with the notice of failure until approval to remove the notice of failure is received from the department [agency].

(7) Facilities that receive a severity level I violation and are deemed a serious risk to human health must [shall] notify patients as specified in (q)(2) of this section. [on whom the facility performed a mammogram during the period in which the system failed to meet the agency's certification standards. The facility shall:]

[(A) inform the patient that the mammography system failed to satisfy the agency certifying body's standards;]

[(B) recommend that the patient consult with the patient's physician regarding the need for another mammogram; and]

[(C) list the three facilities closest to the original testing facility that have a certified mammography system.]

(8) In addition to the requirements of paragraph (7) of this subsection, the department [agency] may require a facility to notify a patient of any other failure of the facility's mammography system to meet the department's [agency's] certification standards.

(9) The patient notification must [shall] include the following:

(A) an explanation of the mammography system failure to the patient; and

(B) the potential consequences to the mammography patient.

(10) The facility must [registrant shall] make a record of the mammography patients notified as specified in [accordance with] paragraphs (7) and (8) of this subsection for inspection by the department [agency].

(A) The record must [records shall] include the name and address of each mammography patient notified, date of notification, and a copy of the text sent to the individual.

(B) The record must [records shall] be maintained as specified in [accordance with] subsection (x) [(ee)] of this section.

(w) [(gg)] Requirements for interventional breast radiography machines.

[(1) Prohibitions.]

[(A) The agency may prohibit use of interventional breast radiography machines that pose a significant threat or endanger public health and safety, in accordance with §289.231 and §289.205 of this title.]

[(B) Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed physician. The provision specifically prohibits intentional exposure of an individual for training, demonstration, or other non-healing arts purposes.]

[(2) Exemptions.]

[(A) Machines used exclusively for interventional breast radiography are not required to be accredited by an FDA-approved accreditation body.]

[(B) Loaner machines as described in subsection (n)(6) of this section are exempt for the inspection requirements in subsection (ff) of this section.]

[(C) All interventional breast radiography registrants are exempt from the posting of radiation area requirements of §289.231(x) of this title provided that the operator has continuous surveillance and access control of the radiation area.]

(1) [(3)] Interventional [Requirements for interventional] breast radiography machine certificate of registration (COR) [certification].

(A) A person who receives, possesses, uses, owns, or acquires [Each person having] an interventional breast radiography machine must apply for a certificate of registration as specified [shall submit an application] in [accordance with] §289.226(e) [(1) - (3), (5), and (7)] of this subchapter, relating to general requirements for application and registration [title], and must [shall] receive a COR [certification] from the department before using an interventional breast radiography machine on humans [agency within 30 days of beginning use].

(B) An application for a COR must [certification shall] be signed by:

(i) a licensed physician, and

(ii) the RSO [applicant and the RSO].

(C) An application for a COR [certification] may contain information on multiple interventional breast radiography machines. Each machine must be identified by referring to the machine's manufacturer, model name, and serial number located on the control panel.

(D) Each applicant must [shall] submit documentation of [evidence that] a [medical physicist's] survey [has been] performed by a medical physicist, as specified in [accordance with] paragraph (11)[(13)] of this subsection.

(2) [(4)] Issuance of a certificate of registration [certification].

(A) [Certification.] A COR [certification] for interventional breast radiography machines will be issued if the department [agency] determines the [that an] application meets the requirements of the Act and [the requirements of] this chapter. The COR [certification] authorizes the proposed operations and includes [activity in such form and contains such] conditions and limitations [as] the department [agency] deems [appropriate or] necessary.

(B) Conditions [~~Requirements and conditions~~]. The department [~~agency~~] may incorporate in the COR [~~certification~~] at the time of issuance, or [~~thereafter~~] by amendment, [~~such~~] additional requirements and conditions for [~~with respect to~~] the facility's [~~registrant's~~] possession, use, and transfer of radiation machines [~~subject to this chapter as it deems appropriate or~~] necessary [~~in order~~] to:

(i) minimize danger to occupational and public health and safety;

(ii) require additional reports and maintain [~~the keeping of~~] additional records as [~~may be appropriate or~~] necessary; and

(iii) prevent loss or theft of radiation machines subject to this section.

(C) Additional information. The department [~~agency~~] may request[~~, and the registrant shall provide,~~] additional information after the certification has been issued to enable the department [~~agency~~] to determine whether the certification should be modified as specified in [~~accordance with~~] §289.226(r) of this subchapter relating to renewal of a certificate of registration [~~title~~].

(3) [~~(5)~~] Modification, suspension, or revocation of the certificate of registration [~~certification~~]. Modification, suspension, or revocation of the COR must occur as specified [~~certification shall be~~] in [~~accordance with~~] §289.226(s)[~~(r)~~] of this subchapter [~~title~~].

(4) [~~(6)~~] Specific terms and conditions of the certificate of registration [~~certification~~]. Specific terms and conditions of the COR, as specified [~~certification shall be~~] in [~~accordance with~~] §289.226 [~~(l)~~] of this subchapter, must be followed [~~title~~].

(5) Renewal of certification. The registrant must file an application for renewal of the COR as follows.

(A) A person who receives, possesses, uses, owns, or acquires an interventional breast radiography machine must apply for renewal as specified in §289.226(e)(1) - (3), (5), and (7) of this subchapter.

(B) An application for renewal must be signed by a licensed physician and the RSO.

(C) An application for renewal must include a medical physicist's survey as specified in paragraph (11) of this subsection.

(D) If a registrant files an application for renewal in proper form at least 30 days before the existing certification expires, the existing certification does not expire until the application status has been determined by the department.

(6) Expiration of the certificate of registration.

(A) COR of an interventional breast radiography machine expires at the end of the day in the month and year stated on the certificate. Expiration of the COR does not relieve the registrant of the requirements of this chapter.

(B) If a registrant does not apply for renewal of the certification under paragraph (8) of this subsection, as applicable, the registrant must:

(i) terminate use of all interventional breast radiography machines;

(ii) pay any outstanding fees as specified in §289.204 of this chapter; and

(iii) submit a record of the disposition of the interventional breast radiography machine to the department. If the machine was transferred, include to whom it was transferred.

(7) Each diagnostic review workstation (RWS) used to interpret images must follow manufacturer specifications for display conditions and quality control. If the RWS manufacturer does not specify QC procedures, then a QA program that is substantially the same as the QA program recommended by the image receptor manufacturer must be established and followed.

(8) Renewal of certification. The registrant shall file an application for renewal of certification as follows.

(A) Each person having an interventional breast radiography machine shall submit an application for renewal in accordance with §289.226(e)(1) - (3), (5), and (7) of this title.

(B) An application for renewal shall be signed by the RSO, licensed physician, and the applicant.

(C) An applicant for renewal shall submit a medical physicist's survey in accordance with paragraph (13) of this subsection.

(D) If a registrant files an application for renewal in proper form at least 30 days before the existing certification expires, such existing certification shall not expire until the application status has been determined by the agency.

(9) Expiration of certification.

(A) Each certification of interventional breast radiography machine expires at the end of the day in the month and year stated on the certificate. Expiration of the certification does not relieve the registrant of the requirements of this chapter.

(B) If a registrant does not submit an application for renewal of the certification under paragraph (8) of this subsection, as applicable, the registrant shall on or before the expiration date specified in the certification:

(i) terminate use of all interventional breast radiography machines;

(ii) pay any outstanding fees in accordance with §289.204 of this title; and

(iii) submit a record of the disposition of the interventional breast radiography machine(s) to the agency. If the machine(s) was transferred, include to whom it was transferred.

(10) Termination of certification. When a registrant decides to terminate all activities involving interventional breast radiography machine(s) authorized under the certification, the registrant shall notify the agency immediately and do the following:

(A) request termination of the certification in writing signed by the RSO, owner, or an individual authorized to act on behalf of the registrant;

(B) pay any outstanding fees in accordance with §289.204 of this title; and

(C) submit a record of the disposition of the interventional breast radiography machine(s) to the agency certifying body. If the machine(s) was transferred, include to whom it was transferred.

(11) Personnel requirements.

(A) A medical radiologic technologist (operators of equipment) shall hold a current general certificate in accordance

with the Medical Radiologic Technologist Certification Act, Texas Occupations Code, Chapter 601.

(B) A medical physicist shall hold a current Texas license under the Medical Physics Practice Act, Texas Occupations Code, Chapter 602, in diagnostic radiological physics and be registered with the agency or employed by an entity registered with the agency, in accordance with §289.226(j) of this title and the Act, unless exempted by §289.226(d)(6) of this title.

(12) Requirements to have a written quality assurance program. Requirements to have a written quality assurance program as described by the manufacturer and/or the medical physicist to ensure the safety, reliability, clarity, and accuracy of services performed at the facility shall comply with the following.

(A) If any failures are noted, corrective actions shall be taken within the time frame indicated/established by the manufacturer or medical physicist. In the event, that no time frames are indicated, corrective action shall be completed within 30 days of the failure.

(B) If any component tested fails the dosimetry test, the corrective action will be taken before any further interventional breast radiography examinations are performed.

(13) Interventional breast radiography machine evaluations and annual survey.

(A) Interventional breast radiography machines are required to have a medical physicist perform a survey:

(i) whenever a new interventional breast radiography machine is installed, disassembled, and reassembled at the same or a new location;

(ii) whenever major components of an interventional breast radiography machine are changed or repaired; and

(iii) on an annual basis.

(B) The following quality assurance tests shall be performed: AEC, kVp, focal spot condition, HVL, collimation, alignments, and dosimetry tests in accordance with subsection (v)(5)(A) - (G) of this section.

(C) The medical physicist shall provide the facility with a preliminary oral or written report of deficiencies within 72 hours of the survey if it involves dosimetry.

(D) The medical physicist shall prepare a written report for the facility within 30 days of the date of the survey to include the following:

(i) a written survey report that includes a summary of the tests performed, all test conditions, specifications, results, and recommendations for corrective actions; and

(ii) date and signature of the medical physicist performing or supervising the survey. If the survey was performed entirely or in part by another individual under the direct supervision of the medical physicist, that individual and the part of the survey that individual performed shall also be identified in the survey.

(14) Operating and safety procedures. Each registrant shall have and implement written operating and safety procedures that shall be made available to each individual operating x-ray equipment, including any restrictions of the operating technique required for the safe operation of the particular system. These procedures shall include, but are not limited to:

(A) posting notices to workers in accordance with §289.203(b) of this title;

(B) instructions to workers in accordance with §289.203(c) of this title;

(C) notifications and reports to individuals in accordance with §289.203(d) of this title;

(D) ordering x-ray exams in accordance with §289.231(b) of this title;

(E) occupational dose requirements in accordance with §289.231(m) of this title;

(F) personnel monitoring requirements in accordance with §289.231(n) and (q) of this title;

(G) credentialing requirements for medical radiologic technologists, and medical physicists in accordance with paragraph (11) of this subsection;

(H) use of a technique chart in accordance with paragraph (22) of this subsection;

(I) exposure of individuals other than the patient in accordance with paragraph (18) of this subsection; and

(J) holding of patients or image receptors in accordance with subsection (dd)(7) of this section.

(15) Receipt, transfer, and disposal of interventional breast radiography machines. Each registrant shall maintain records showing the receipt, transfer, and disposal of interventional breast radiography machines. These records shall include the date of receipt, transfer, or disposal; the name and signature of the individual making the record; and the manufacturer's model name and serial number on the control panel. These records shall be maintained in accordance with subsection (ee) of this section for inspection by the agency.

(16) Calibration, maintenance, and modifications. Each registrant shall maintain records showing calibrations, maintenance, and modifications performed on each interventional breast radiography machine. These records shall include the date of the calibration, maintenance, or modification performed; the name of the individual making the record; and the manufacturer's model name and serial number on the control panel. These records shall be maintained in accordance with subsection (ee) of this section for inspection by the agency.

(17) Viewing system. Windows, mirrors, closed circuit television, or an equivalent system shall be provided to permit the operator to continuously observe the patient during irradiation. The operator shall be able to maintain verbal, visual, and aural contact with the patient.

(18) Exposure of individuals other than the patient. Only the staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiation exposure unless such individual's assistance is required.

~~[(19) Maintenance of records. Maintenance of applicable records in subsection (ee) of this section.]~~

~~[(20) Inspection requirements. Inspection requirements in accordance with subsection (ff)(2) - (4) of this section.]~~

~~[(21) Equipment requirements. Equipment requirements in accordance with §289.227(h) of this title (relating to Use of Radiation Machines in the Healing Arts).]~~

(19) [~~(22)~~] Technique chart. A chart or manual must [~~shall~~] be provided or electronically displayed in the vicinity of the control panel of each interventional breast radiography machine that specifies

technique factors used for a [~~to be utilized versus~~] patient's anatomical size. The technique chart must [~~shall~~] be used by all operators.

(x) Record requirements. Records specified in this section must be maintained for inspection by the department as specified in paragraph (3) of this subsection. Records may be maintained electronically as specified in §289.231(ff)(3) of this subchapter.

(1) Records for mammography machines authorized for mobile service operations.

(A) Copies of the following must be kept with mammography machines authorized for mobile services:

(i) OSP as specified in subsection (t)(1) of this section;

(ii) operator's credentials;

(iii) current quality control records for at least the last 90 calendar days for on-board processors as specified in subsection (l)(1) of this section;

(iv) current copies of §289.203, §289.226, §289.230, and §289.231 of this chapter;

(v) copy of certification;

(vi) certification of inspection as specified in subsection (v)(5) of this section;

(vii) notice of failure from last inspection as specified in subsection (v)(6) of this section, if applicable; and

(viii) copy of mammography accreditation.

(B) Copies of all other records specified in this section must be maintained at a specified location.

(2) Records required at separate authorized use locations. Copies of the following must be kept at each separate authorized use location:

(A) credentialing, continuing education, and continuing experience records for IPs, MRTs, and medical physicists operating at the location specified in subsection (h) of this section;

(B) mandatory training records for IPs and medical physicists operating at the location specified in subsection (h) of this section, if applicable;

(C) current physicist annual survey of the mammography system;

(D) current copies of §289.203, §289.226, §289.230, and §289.231 of this chapter;

(E) copy of certification;

(F) QA program as specified in subsections (k), (l), and (m) of this section;

(G) quality control records as specified in subsection (k)(2) of this section;

(H) OSP as specified in subsection (t)(1) of this section;

(I) records of receipts, transfers, and disposal as specified in subsection (u)(3) of this section;

(J) calibration, maintenance, and modification records as specified in subsection (t)(8) of this section;

(K) certification of inspection as specified in subsection (v)(5) of this section;

(L) notification of failure as specified in subsection (v)(6), if applicable;

(M) records of notification of patients as specified in subsection (v)(10) this section; and

(N) copy of mammography accreditation.

(3) Retention requirements for record keeping. Time requirements for record keeping must be according to the following chart. Figure: 25 TAC §289.230(x)(3)

[~~(hh) Appendices.~~]

[~~(1) Subjects to be included in mammography training for medical radiologic technologists shall include, but not be limited to, the following:~~]

[~~(A) breast anatomy and physiology;~~]

[~~(B) positioning and compression;~~]

[~~(C) quality assurance/quality control techniques;~~]

[~~(D) imaging of patients with breast implants; and~~]

[~~(E) at least eight hours of training in each mammography modality to be used by the technologist in performing mammography exams.~~]

[~~(2) Subjects to be included in mammography training for interpreting physicians shall include, but not be limited to, the following:~~]

[~~(A) radiation physics, including radiation physics specific to mammography;~~]

[~~(B) radiation effects;~~]

[~~(C) radiation protection; and~~]

[~~(D) interpretation of mammograms. This shall be under the direct supervision of a physician who meets the requirements of subsection (r)(1) of this section.~~]

[~~(3) Operating and safety procedures. The registrant's operating and safety procedures shall include, but are not limited to, the following procedures as applicable:~~]

[~~(A) posting notices to workers in accordance with §289.203(b) of this title;~~]

[~~(B) instructions to workers in accordance with §289.203(c) of this title;~~]

[~~(C) notifications and reports to individuals in accordance with §289.203(d) of this title;~~]

[~~(D) ordering x-ray exams in accordance with §289.231(b) of this title;~~]

[~~(E) occupational dose requirements in accordance with §289.231(m) of this title;~~]

[~~(F) personnel monitoring requirements in accordance with §289.231(n) and (q) of this title;~~]

[~~(G) posting of a radiation area in accordance with §289.231(x) and (y) of this title;~~]

[~~(H) credentialing requirements for lead interpreting physicians, interpreting physicians, medical radiologic technologists, and medical physicists in accordance with subsection (r) of this section;~~]

[~~(I) retention of clinical images in accordance with subsection (t)(4) of this section;~~]

[(J) quality assurance program in accordance with subsections (u) - (w) of this section;]

[(K) image quality and corrective action for images of poor quality in accordance with subsection (u)(1)(B)(i) of this section;]

[(L) repeat analysis in accordance with subsection (v)(3)(B) of this section;]

[(M) procedures and techniques for mammography patients with breast implants in accordance with subsection (x) of this section;]

[(N) procedure to handle complaints in accordance with subsection (y) of this section;]

[(O) self-referral mammography in accordance with subsection (bb) of this section;]

[(P) use of a technique chart in accordance with subsection (dd)(2) of this section;]

[(Q) exposure of individuals other than the patient in accordance with subsection (dd)(5) of this section;]

[(R) use of protective devices in accordance with subsection (dd)(6) of this section; and]

[(S) holding of patients or image receptors in accordance with subsection (dd)(7) of this section.]

[(4) Phantom image scoring protocol for film-screen modality. Each of the following object groups are to be scored separately. In order to receive a passing score on the phantom image, all three test object groups must pass. A failure in any one of the areas results in a phantom failure.]

[(A) Fibers. A score of 4.0 for fibers is required to meet the evaluation criteria. The diameter size of fibers are 1.56 mm, 1.12 mm, 0.89 mm, 0.75 mm, 0.54 mm, and 0.40 mm. Score the fibers as follows.]

[(i) Begin with the largest fiber and move down in size, adding one point for each full fiber until a score of zero or one half is given. Stop counting at the first point where you lose visibility of objects.]

[(ii) If the entire length of the fiber can be seen and its location and orientation are correct, that fiber receives a score of one.]

[(iii) If at least half, but not all, of the fiber can be seen and its location and orientation are correct, that fiber receives a score of one half.]

[(iv) If less than one half of a fiber can be seen or if the location or orientation are incorrect, that fiber receives a score of zero.]

[(v) After determining the last fiber to be counted, look at the overall background for artifacts. If there are background objects that are fiber-like in appearance and are of equal or greater brightness than the last visible half or full fiber counted, subtract the last half or full fiber scored.]

[(B) Speck groups. A score of 3.0 for speck groups is required to meet the evaluation criteria. Diameter sizes of speck groups are 0.54 mm, 0.40 mm, 0.32 mm, 0.24 mm, and 0.16 mm. There are six specks per group. Score the speck groups as follows.]

[(i) Begin with the largest speck group and move down in size adding one point for each full speck group until a score of one half or zero is given, then stop.]

[(ii) If at least four of the specks in any group are visualized, the speck group is scored as one.]

[(iii) If two or three specks in a group are visualized, the score for the group is one half.]

[(iv) If one speck or no specks from a group are visualized, the score is zero.]

[(v) After determining the last speck group to receive a full or one-half point, look at the overall background for artifacts. If there are speck-like artifacts within the insert region of the phantom that are of equal or greater brightness than individual specks counted in the last visible half or full speck group counted, subtract the artifact speck from the observed specks in the last group scored, one by one. Note that the highest number of speck-like artifacts that can potentially be subtracted is the number of visible specks that were scored in the last group. Repeat the scoring of the last visible speck group after these deductions.]

[(C) Masses. A score of 3.0 is required to meet the evaluation criteria. Diameter sizes of masses are 2.00 mm, 1.00 mm, 0.75 mm, 0.50 mm, and 0.25 mm. Score the masses as follows.]

[(i) Begin with the largest mass and add one point for each full mass observed until a score of one half or zero is assigned.]

[(ii) Score one for each mass that appears as a minus density object in the correct location that can be seen clearly enough to observe round, circumscribed borders.]

[(iii) Score one half if the mass is clearly present in the correct location, but the borders are not visualized as circular.]

[(iv) After determining the last full or half mass to be counted, look at the overall background for artifacts. If there are background objects that are mass-like in appearance and are of equal or greater visibility than the last visible mass, subtract the last full or half point assigned from the original score.]

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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Cynthia Hernandez
General Counsel
Department of State Health Services
Earliest possible date of adoption: March 23, 2025
For further information, please call: (512) 834-6655

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25 TAC §289.234

STATUTORY AUTHORITY

The repeal 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 regulations; §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 relating to inspection of x-ray equipment; Chapter 401, Subchapter J, which authorizes enforcement of the Act; Chapter 401, Subchapter L, which provides for the Certification of Mammography Systems;

and Texas Government Code §531.0055 and Texas Health and Safety Code §1001.075, which authorize the Executive Commissioner of HHSC to adopt rules and policies for the operation and provision of health and human services by DSHS and the administration of Texas Health and Safety Code Chapter 1001.

§289.234. Mammography Accreditation.

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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Cynthia Hernandez
General Counsel
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TITLE 26. HEALTH AND HUMAN SERVICES

PART 1. HEALTH AND HUMAN SERVICES COMMISSION

CHAPTER 257. CASE MANAGEMENT FOR CHILDREN AND PREGNANT WOMEN

The Executive Commissioner of the Texas Health and Human Services Commission (HHSC) proposes new §257.1, concerning Purpose and Application; §257.3, concerning Definitions; §257.5, concerning Client Eligibility; §257.7, concerning Client Rights; §257.9, concerning Client Confidentiality; §257.11, concerning Components of Case Management for Children and Pregnant Women Services; §257.15, concerning Provider Qualifications and Approval Process; §257.17, concerning Provider Responsibilities; §257.19, concerning Case Manager Qualifications; §257.21, concerning Case Manager Responsibilities; and §257.23, concerning Compliance with Utilization Reviews and Quality Assurance Reviews and Overpayments.

BACKGROUND AND PURPOSE

Case Management for Children and Pregnant Women (CPW) services assist eligible Medicaid clients in gaining access to necessary medical, social, educational, and other services related to the client's health conditions and health risks. To be eligible for services, a client must be either a child with a health condition or health risk or a pregnant woman with a high-risk condition. The client must also be Medicaid-eligible in Texas, need case management for CPW services, and choose such services.

HHSC proposes to repeal Chapter 27, Case Management for Children and Pregnant Women, in Title 25, Part 1, Texas Administrative Code (TAC), and proposes a new Chapter 257, Case Management for Children and Pregnant Women, in Title 26, Part 1, TAC. The purpose for moving the CPW rules from Title 25 to Title 26 is to conform administrative rules to current HHSC practices based on Senate Bill (S.B.) 200, 84th Legislature, Regular Session, 2015. S.B. 200 consolidated functions in the Texas Health and Human Services delivery system and transferred programs, to include CPW, from the Department of State Health Services (DSHS) to HHSC. The repeal of the CPW rules in 25 TAC Chapter 27 is proposed elsewhere in this issue of the *Texas Register*.

In addition to relocating the CPW rules from DSHS to HHSC, the proposal makes amendments to the CPW rules in accordance with House Bill (H.B.) 133, 87th Legislature, Regular Session, 2021, that directs HHSC to deliver CPW services through managed care organizations (MCOs). The proposal also makes amendments to the CPW rules to implement certain requirements of House Bill (H.B.) 1575, 88th Legislature, Regular Session, 2023. H.B. 1575 authorizes case management services to pregnant women with a high-risk condition to address nonmedical needs; adds two new provider types, doula and community health worker, as eligible to provide CPW services; and establishes CPW provider qualifications for doulas and community health workers. The proposal also updates the CPW rules with appropriate references and terminology and includes organizational and minor editing changes for clarity.

SECTION-BY-SECTION SUMMARY

Sections 27.1 through 27.27 in Title 25, Part 1, TAC are repealed and replaced by sections 257.1 through 257.23 in Title 26, Part 1, TAC, except that sections 27.13 and 27.27 were repealed and not replaced.

New Subchapter A, General Provisions

Proposed new §257.1, Purpose and Application, replaces repealed §27.1 and summarizes the purpose of CPW services. The proposed rule differs from the repealed rule by removing references to the Department State Health Services and clarifying that the rules apply to fee-for-service and managed care clients.

Proposed new §257.3, Definitions, replaces repealed §27.3 and explains the meaning of terms used in the rules. The proposed rule differs from the repealed rule by adding new definitions for face-to-face, HHSC, nonmedical need, and provider. The proposed rule amends the definition for access by adding a reference to nonmedical needs. The proposed rule also removes definitions for active providers, application process, prior authorization, and state because the terms are no longer used in the proposed new Chapter 257.

New Subchapter B, Client Services

Proposed new §257.5, Client Eligibility, replaces repealed §27.5 and defines who qualifies to receive the services. The proposed rule differs from the repealed rule by clarifying that a client chooses, rather than desires, to receive CPW services.

Proposed new §257.7, Client Rights, replaces repealed §27.7 and establishes that a client's use of case management services in CPW is voluntary. The proposed rule provides a client the right to actively participate in case management decisions, receive services free from abuse or harm, have the freedom to choose a provider, and request a fair hearing. The proposed rule differs from the repealed rule by clarifying that a client who receives CPW services through an MCO must exhaust internal MCO appeals before requesting a fair hearing.

Proposed new §257.9, Client Confidentiality, replaces repealed §27.9 and defines the circumstances in which client information can and cannot be shared.

Proposed new §257.11, Components of Case Management for Children and Pregnant Women Services and Reimbursement, replaces repealed §27.11 and outlines the services that are provided and the components that are billable. The proposed rule differs from the repealed rule by adding that a service plan must

be signed by the Medicaid provider. The proposal also adds nonmedical needs as a component of CPW and updates requirements for follow-up visits by a case manager. The proposal also removes references to prior authorization and adds that services are not reimbursable when a client is an inpatient at a hospital or other treatment facility.

New Subchapter C, Provider Qualifications and Responsibilities

Proposed new §257.15, Provider Qualifications and Approval Process, replaces repealed §§27.15 and 27.17 and indicates the steps necessary to become a provider of services. The proposed rule differs from the repealed rule by updating a reference to the U.S. HHS Office of Inspector General List of Excluded Individuals/Entities (LEIE); clarifying that interested providers must complete a pre-planning process with HHSC; adding a requirement that providers must complete the HHSC standardized case management training provided by HHSC; and generally condensing the approval process. The proposed rule also differs from the repealed rule by removing references to response times and Medicaid claims administrator and the requirement for a new application if twelve months have lapsed since initial approval was received.

Proposed new §257.17, Provider Responsibilities, replaces repealed §27.19 and specifies what providers must do to maintain the duties of providing services through CPW, including outreach activities.

Proposed new §257.19, Case Manager Qualifications, replaces repealed §27.21 and specifies qualifications to be a case manager in CPW. The proposed rule differs from the repealed rule by adding references to the Texas Occupations Code for advanced practice registered nurse, registered nurse, and social worker and adding community health worker and doula to the list of provider qualifications as required by H.B. 1575.

Proposed new §257.21, Case Manager Responsibilities, replaces repealed §27.23 and describes the requirement to have appropriate and current licensure or certification, provide services convenient to a client, and coordinate services.

Proposed new §257.23, Compliance with Utilization Reviews and Quality Assurance Reviews and Overpayments, replaces repealed §27.25 and explains that the purpose of a utilization review is to ensure fiscal integrity and describes the providers' responsibility in participating in quality and utilization reviews. The proposed rule differs from the repealed rule by requiring providers to ensure services to a client are within the scope of the client's service plan; referencing quality assurance and utilization reviews without specifying frequency or timeline for the reviews as compared to reviews being conducted each fiscal year; and removing reference to reviews of inactive providers. The proposed rule also replaces references to "the department" with references to HHSC.

FISCAL NOTE

Trey Wood, HHSC Chief Financial Officer, has determined that for each year of the first five years that the rule will be in effect, there will be an estimated additional cost to state government as a result of enforcing and administering the rules as proposed. Enforcing or administering the rules does 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 cost of $665,000 in State Funds and $665,000 in Federal Funds for fiscal year (FY) 2024, $0 in FY 2025, $0 in FY 2026, $0 in FY 2027, and $0 in FY 2028.

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 result in no assumed change in future legislative appropriations;

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

(5) the proposed rules will create new regulations;

(6) the proposed rules will not expand, limit or repeal existing regulations;

(7) the proposed rules will increase the number of individuals subject to the rules; and

(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 to comply with the proposed new rules because provider and client participation in CPW is optional.

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 and are necessary to implement legislation that does not specifically state that §2001.0045 applies to the rules.

PUBLIC BENEFIT AND COSTS

Emily Zalkovsky, State Medicaid Director, has determined that for each year of the first five years the rules are in effect, the public benefit will be having a greater number of providers available for CPW clients to choose from.

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 provider and client participation in CPW services is optional.

TAKINGS IMPACT ASSESSMENT

HHSC has determined that the proposal does not restrict or limit an owner's right to the owner's 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 4601 West Guadalupe Street, 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 faxing or emailing comments, please indicate "Comments on Proposed Rule 24R049" in the subject line.

SUBCHAPTER A. GENERAL PROVISIONS

26 TAC §257.1, §257.3

STATUTORY AUTHORITY

The new sections are authorized by Texas Government Code §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of services by the health and human services agencies; Texas Government Code §531.033, which authorizes the Executive Commissioner of HHSC to adopt rules as necessary to carry out the commission's duties; and Human Resources Code §32.021 and Texas Government Code §531.021(a), which authorize HHSC to administer the federal medical assistance (Medicaid) program.

The new sections implement Texas Government Code §531.651, §531.652, §531.653, §531.654, §531.655, and §531.656.

§257.1. Purpose and Application.

(a) Case Management for Children and Pregnant Women is a Medicaid benefit that assists an eligible client in gaining access to the necessary medical, social, educational, and other service needs related to a child with a health condition or health risk or a pregnant woman with a high-risk condition.

(b) The rules in this chapter apply to Case Management for Children and Pregnant Women services delivered in fee-for-service and through a Medicaid managed care organization.

§257.3. Definitions.

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

(1) Access--The ability of an eligible client to obtain health and health-related services and other services related to nonmedical needs, as determined by factors such as:

(A) the availability of Texas Health Steps services;

(B) service acceptability to the eligible child, pregnant woman, or both;

(C) the location of health care facilities and other resources;

(D) transportation;

(E) hours of facility operation; and

(F) length of time available to see providers of health and health-related services or other services related to nonmedical needs.

(2) Applicant--An agency, organization, or individual who submits an application to enroll as a state Medicaid provider of Case Management for Children and Pregnant Women services.

(3) Case manager--An individual qualified under §257.19 of this title (relating to Case Manager Qualifications) who provides Case Management for Children and Pregnant Women services. A case manager may be an independent provider or an employee or contractor of a Medicaid-enrolled case management provider.

(4) Case management services--Services provided under this chapter to an eligible client to assist the client in gaining access to necessary medical, social, educational, and other services for a child with a health condition or health risk or a pregnant woman with a high-risk condition. In this chapter, these services are also referred to as Case Management for Children and Pregnant Women services.

(5) Child with a health condition or health risk--A child from birth through 20 years of age who has or is at risk for a medical condition, illness, injury, or disability that results in limitation of function, activities, or social roles in comparison with healthy peers of the same age in the general areas of physical, cognitive, emotional, or social growth and development.

(6) Client--An individual who is eligible for and enrolled in the Texas Medicaid Program and meets the eligibility requirements listed in §257.5 of this chapter (relating to Client Eligibility) or the client's parent or legal guardian.

(7) Client choice--A client is given the freedom to choose a provider, to the extent possible, from among providers available to the client.

(8) Face-to-face--A visit conducted by a case manager with a client in person or utilizing synchronous audiovisual communications.

(9) Family--A basic unit in society having at its nucleus:

(A) one or more adults living together and cooperating in the care and rearing of the adult's or adults' biological or adopted children; or

(B) a person or persons acting as an individual's family, foster family, guardian, or identifiable support person or persons.

(10) Health and health-related services--Services that are provided to meet the preventive, primary, tertiary, and specialty health needs of an eligible client, including, medical and dental checkups, immunizations, acute care visits, pediatric specialty consultations, physical therapy, occupational therapy, audiology, speech language services, mental health professional services, pharmaceuticals, medical supplies, prenatal care, family planning, adolescent preventive health, durable medical equipment, nutritional supplements, prosthetics, eyeglasses, and hearing aids.

(11) HHSC--The Texas Health and Human Services Commission or its designee, including a Medicaid managed care organization.

(12) High-risk condition--Applies to a woman who is pregnant and has a medical or psychosocial condition that places the woman and the woman's fetus at a greater than average risk for complications, either during pregnancy, delivery, or after birth.

(13) Medicaid--Medical assistance program implemented by the state under the provisions of Title XIX of the Social Security Act, as amended, at 42 U.S.C., §1396, et seq.

(14) Nonmedical need--Nonmedical drivers of health are the conditions in the place where a person lives, learns, works, and plays and that affect a wide range of health risks and outcomes.

(15) Provider--May be:

(A) an agency approved by HHSC to provide Case Management for Children and Pregnant Women services and that is enrolled as a Medicaid provider; or

(B) an individual approved by HHSC to provide Case Management for Children and Pregnant Women services and who is enrolled as a Medicaid provider.

(16) Quality assurance review--A review conducted by HHSC of a provider's client records, internal quality assurance policy, outreach materials, and compliance with HHSC's rules and policies, including the qualifications of the provider's case managers as listed in §257.19 of this chapter.

(17) TMPPM--Texas Medicaid Provider Procedures Manual.

(18) Utilization review--A review conducted by HHSC of a provider's claims data in which trends have been identified that could indicate potential concerns with the delivery of case management services.

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
Chief Counsel
Health and Human Services Commission
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For further information, please call: (512) 438-2910

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SUBCHAPTER B. CLIENT SERVICES

26 TAC §§257.5, 257.7, 257.9, 257.11

STATUTORY AUTHORITY

The new sections are authorized by Texas Government Code §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of services by the health and human services agencies; Texas Government Code §531.033, which authorizes the Executive Commissioner of HHSC to adopt rules as necessary to carry out the commission's duties; and Human Resources Code §32.021 and Texas Government Code §531.021(a), which authorize HHSC to administer the federal medical assistance (Medicaid) program.

The new sections implement Texas Government Code §531.651, §531.652, §531.653, §531.654, §531.655, and §531.656.

§257.5. Client Eligibility.

A client eligible for services under this chapter must be either a child with a health condition or health risk or a pregnant woman with a high-risk condition who:

(1) is Medicaid-eligible in Texas;

(2) is in need of Case Management for Children and Pregnant Women services; and

(3) chooses such services.

§257.7. Client Rights.

(a) Use of services is voluntary. Acceptance or refusal of services does not affect eligibility for or receipt of any other Medicaid services, or for future case management services.

(b) All records about a client are considered confidential information, in accordance with the standards and requirements described in §257.9 of this subchapter (relating to Client Confidentiality).

(c) A client has the right to:

(1) actively participate in case management decisions, including the right to refuse services from a case manager;

(2) receive services free from abuse or harm from a case manager;

(3) have freedom of choice to choose a provider in the client's county of residence or service area, as applicable;

(4) have freedom to request a transfer to another available case manager at any time; and

(5) except as described in subsection (d) of this section, request a fair hearing, conducted in accordance with the rules in 1 TAC, Chapter 357, Subchapter A (relating to Uniform Fair Hearing Rules), within 90 days after receiving written notification that services have been denied, reduced, suspended, or terminated.

(d) A client receiving Case Management for Children and Pregnant Women services through a Medicaid managed care organization (MCO) must:

(1) use the MCO's complaint and appeal procedure as prescribed in 1 TAC §353.415 (relating to Member Complaint and Appeal Procedures); and

(2) exhaust internal MCO appeals before requesting a fair hearing as described in subsection (c)(5) of this section.

§257.9. Client Confidentiality.

(a) Federal and state laws and regulations prohibit the disclosure of information about a Medicaid client without effective consent by the client or the client's parent or legal guardian, except for purposes directly connected with the administration of the Medicaid program, as described in:

(1) 42 U.S.C. §1396a(a)(7);

(2) 42 C.F.R. §§431.301 - 431.306;

(3) Texas Human Resources Code §12.003 and §21.012; and

(4) Texas Government Code §552.101.

(b) A provider is not considered directly connected with the administration of the program. Although a provider is not entitled to confidential information without prior consent, the provider may verify a client's eligibility status.

(c) An entity with which HHSC contracts to perform certain administrative functions, including contractors for outreach, informing, and transportation services, may receive confidential information without a client's consent, but only to the extent necessary to perform and administer the contract. A contracted entity is bound by the same standards of confidentiality applicable to the Medicaid program, and the entity must provide effective safeguards to ensure confidentiality.

§257.11. Components of Case Management for Children and Pregnant Women Services.

The following are the essential components of Case Management for Children and Pregnant Women services and an explanation of billable components.

(1) Intake--A case manager's visit with a client, family, or guardian that includes the case manager collecting demographic infor-

mation, health information, and other information relevant to determining the client's eligibility.

(2) Comprehensive visit--A required visit conducted by a case manager face-to-face with a client, family, or guardian that includes the case manager completing the following:

(A) Family Needs Assessment. A comprehensive assessment completed by a case manager to determine a client's need for any medical, educational, social, or other services required to address the client's short- and long-term health and well-being. A case manager must document this assessment on a Family Needs Assessment form, which must include:

(i) taking a client's history;

(ii) identifying the client's needs, assessing and addressing family issues that impact the client's health condition, health risk, high-risk condition, or nonmedical needs; and

(iii) gathering information from other sources, such as family members, medical providers, social workers, and educators, if necessary, to form a complete assessment of the client.

(B) Service Plan. A plan for case management services completed by a case manager with a client or the client's parent or legal guardian that determines a planned course of action based on the information collected through the assessment required in paragraph (2)(A) of this section. A case manager must document the Service Plan on a Service Plan form, which must:

(i) include activities and goals developed by the client in consultation with the case manager to address the medical, social, educational, and other services needed by the client;

(ii) identify a course of action to respond to the assessed needs of the client, including identifying the individual responsible for contacting the appropriate service providers, and designating the time frame within which the client should access services; and

(iii) be dated and signed by the Medicaid provider.

(3) Referral and related activities. To help manage a client's care, a case manager making referrals and conducting related activities, such as scheduling appointments for the client, conducting collateral contacts with a non-eligible individual that are directly related to identify and help the client obtain needed services and link the client with:

(A) medical, social, and educational providers; and

(B) other programs and services that can provide services the client needs.

(4) Follow-up visits by a case manager.

(A) A case manager must make a follow-up visit:

(i) as frequently as necessary to ensure a client's Service Plan is implemented and adequately addresses the client's needs;

(ii) annually for a client who is eligible for case management for longer than 12 consecutive months; and

(iii) as needed during the eligible postpartum period for a client who is a pregnant woman with a high-risk condition who may also have nonmedical needs.

(B) During a follow up visit, a case manager must:

(i) determine if:

(I) services have been furnished to a client in accordance with the client's Service Plan; and

(II) services in the initial Service Plan are adequate to address the client's needs; and

(ii) complete a Service Plan Addendum form if the case manager identifies there has been a change in the client's needs or status and the initial Service plan needs to be revised.

(5) The essential components of Case Management for Children and Pregnant Women services that are eligible for Medicaid reimbursement are the comprehensive visit and each follow-up visit performed in accordance with this section.

(6) Case management services are not reimbursable if the services are provided:

(A) to a client who does not meet the client eligibility requirements in §257.5 of this subchapter (relating to Client Eligibility);

(B) to a client who has already received another case management service on the same day from the same billing provider; or

(C) when a client is an inpatient at a hospital or other treatment facility.

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 C. PROVIDER QUALIFICATIONS AND RESPONSIBILITIES

26 TAC §§257.15, 257.17, 257.19, 257.21, 257.23

STATUTORY AUTHORITY

The new sections are authorized by Texas Government Code §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of services by the health and human services agencies; Texas Government Code §531.033, which authorizes the Executive Commissioner of HHSC to adopt rules as necessary to carry out the commission's duties; and Human Resources Code §32.021 and Texas Government Code §531.021(a), which authorize HHSC to administer the federal medical assistance (Medicaid) program.

The new sections implement Texas Government Code §531.651, §531.652, §531.653, §531.654, §531.655, and §531.656.

§257.15. Provider Qualifications and Approval Process.

(a) To be approved by HHSC as a provider, an applicant must:

(1) not be listed on the HHSC Office of Inspector General's Excluded Individual/Entities nor on the U.S. HHS Office of Inspector General List of Excluded Individuals/Entities (LEIE);

(2) complete:

(A) a pre-planning process with HHSC that includes a review of case manager qualifications listed in §257.19 of this subchapter (relating to Case Manager Qualifications) and an overview of case management activities as listed in §257.21 (Case Manager Responsibilities); and

(B) the HHSC standardized case management training provided by HHSC; and

(3) agree to:

(A) employ or contract with one or more case managers who each meet at least one of the qualifications listed in §257.19 of this subchapter (relating to Case Manager Qualifications); and

(B) comply with:

(i) the rules, policies, and procedures of HHSC relating to Case Management for Children and Pregnant Women; and

(ii) applicable state and federal laws governing participation of providers in the Medicaid program and enrollment as a state Medicaid provider.

(b) HHSC notifies an applicant that complies with subsection (a) of this section whether HHSC approves the applicant's enrollment to be a Medicaid provider of Case Management for Children and Pregnant Women services.

§257.17. Provider Responsibilities.

A provider must:

(1) operate in accordance with the laws, rules, regulations, and standards of care relating to the practice of the provider's respective license or certifications;

(2) ensure the provider's case managers operate:

(A) within the laws, rules, regulations, and standards of care relating to the practice of the case manager's respective license, or certification; and

(B) only within the scope of the case manager's respective license or certification;

(3) provide services:

(A) according to policies and procedures as published in the TMPPM and Medicaid bulletins; and

(B) in accordance with the policies and procedures of HHSC;

(4) cease providing services and notify HHSC if the professional license of a case manager is suspended or revoked, with such notification to be provided to HHSC no later than seven calendar days after the date that the suspension or revocation is imposed;

(5) assure that the provider's case managers attend required trainings provided by HHSC;

(6) develop and maintain a quality management system for the provision of services with the primary goal of assisting clients in accessing necessary medical, social, educational, and other services related to the client's health condition, health risk, high-risk condition, or nonmedical need;

(7) ensure that outreach activities:

(A) do not impede freedom of client choice; and

(B) comply with 1 TAC §371.27 (relating to Prohibition against Solicitation of Medicaid or CHIP Recipients); and

(8) ensure that a client is given freedom of choice to choose a provider for case management.

§257.19. Case Manager Qualifications.

A provider that is an agency or an individual approved by HHSC to provide case management services must ensure a case manager meets at least one of the following qualifications:

(1) an advanced practice registered nurse who holds a license, other than a provisional or temporary license, under Texas Occupations Code Chapter 301;

(2) a registered nurse who holds a license, other than a provisional or temporary license, under Texas Occupations Code Chapter 301 and:

(A) has a baccalaureate degree in nursing; or

(B) has an associate degree in nursing and has:

(i) at least two years of cumulative paid full-time work experience; or

(ii) at least two years of cumulative, supervised full-time educational internship or practicum experience obtained in the last 10 years that included assessing the psychosocial and health needs of and making community referrals for:

(I) children up to age 21; or

(II) pregnant women;

(3) a social worker who holds a license, other than a provisional or temporary license, under Texas Occupations Code Chapter 505, appropriate for the individual's practice, including the independent practice of social work;

(4) a community health worker, as defined by Texas Health and Safety Code §48.001, that is certified as a community health worker by the Department of State Health Services; or

(5) a doula who is certified in alignment with nationally recognized standards, as determined by HHSC, unless the doula qualifies as a certified community health worker under paragraph (4) of this subsection.

§257.21. Case Manager Responsibilities.

A case manager must:

(1) comply with all licensure or certification requirements of the appropriate issuing agency or state licensure or examining board, including the obligation to report all suspected child abuse or neglect;

(2) cease providing services and notify HHSC if the case manager's professional license or certification is suspended or revoked, with such notification to be provided to HHSC no later than seven calendar days after the date that the suspension or revocation is imposed;

(3) provide services convenient to a client, either in the client's home, an office setting, or other place of the client's preference; and

(4) have knowledge of, and coordinate services with, providers of health and health-related services, non-covered services, and other active community resources.

§257.23. Compliance with Utilization Reviews and Quality Assurance Reviews and Overpayments.

(a) The purpose of a utilization review and a quality assurance review is:

(1) to ensure program fiscal integrity;

(2) to address the federal mandate requiring program funds be spent only as allowed under federal and state laws and regulations; and

(3) to ensure that a case manager provided Case Management for Children and Pregnant Women services to a client within the scope of the client's Service Plan.

(b) HHSC conducts quality assurance and utilization reviews of all active providers to monitor claims, the quality of case management services, and compliance with Case Management for Children and Pregnant Women rule and policy.

(c) A provider must cooperate with the quality assurance and utilization reviews. A provider will be given notification of upcoming reviews in accordance with the policies and procedures established by HHSC.

(d) If the results of a provider's utilization review or quality assurance review as determined by HHSC, indicates overpayment, HHSC notifies the provider of the overpayment and gives the provider information about how to arrange for repayment.

(e) If a provider becomes aware that the provider received an overpayment, the provider must notify the Medicaid claims administrator to arrange for repayment.

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 28. INSURANCE

PART 1. TEXAS DEPARTMENT OF INSURANCE

CHAPTER 21. TRADE PRACTICES

SUBCHAPTER J. PROHIBITED TRADE PRACTICES

28 TAC §21.1008

The Texas Department of Insurance (TDI) proposes new 28 TAC §21.1008, prohibiting individuals and entities engaged in the business of insurance from tying together the sale of personal automobile policies and residential property policies. Proposed new §21.1008 implements Insurance Code §541.003.

EXPLANATION. Insurance Code §541.003 provides that a "person may not engage in this state in a trade practice that is defined in this chapter as or determined under this chapter to be an unfair method of competition or an unfair or deceptive act or practice in the business of insurance." Insurance Code §541.401 gives the commissioner the authority to "adopt and enforce reasonable rules the commissioner determines necessary to accomplish the purpose of this chapter." Insurance Code §541.001 states that the purpose of Chapter 541 "is to regulate trade practices in the business of insurance by: (1) defining or providing for the determination of trade practices in this state that are unfair methods of competition or unfair or deceptive acts or practices; and (2) prohibiting those trade practices." In addition, Insurance Code §§541.107, 541.201, 541.204, 541.301, 541.351, and 541.352 reinforce that TDI has the authority to adopt and enforce rules that define when a method of competition, act, or practice is considered unfair or unlawful. Also, Insurance Code §31.002(4) and (5) impose on TDI the duty to "protect and ensure the fair treatment of consumers" and "ensure fair competition in the insurance industry in order to foster a competitive market."

Insurance Code Chapter 541 delegates the authority to define acts as unfair or unlawful by rule in order to ensure the public policy of protecting consumers in the business of insurance. This delegation gives TDI the ability to prevent unforeseen, unfair practices that the Legislature cannot conveniently address and assure that the purpose of Chapter 541 is met.

Proposed new §21.1008 implements Insurance Code §541.003 by specifying that making the purchase of a residential property insurance policy contingent on purchasing a personal automobile insurance policy from a specific person, or vice versa, is an unfair act or practice in the business of insurance.

"Tying," also known as "tying arrangements" and "tie-in arrangements," includes "an arrangement whereby a seller sells a product to a buyer only if the buyer purchases another product from the seller." *Black's Law Dictionary* (12th ed., 2024). Tying can also describe when the sale of a product is conditioned on the purchase of another product from a particular person. Proposed new §21.1008 solely addresses business practices where the purchaser does not have a choice of buying the tied products separately. TDI encourages consumers to shop around and compare options to find coverage and pricing that most meet their needs. This rule helps ensure that consumers have the freedom to make the best choices for themselves and their families.

Proposed new §21.1008 does not prohibit insurers or agents offering Texas consumers the option of choosing to purchase personal automobile and residential property policies from the same person. It also does not prohibit insurers offering an actuarially justified premium discount if a consumer chooses to "bundle" multiple products that are separately available for sale. The distinction between bundling discounts and tying can be compared with the practices of a grocer: a grocer may provide a coupon that gives a customer who buys lunch meat a discount on the purchase of bread, but the grocer does not require the customer buying lunch meat to also buy bread.

The rule treats tying and bundling discounts differently because the consumer protection concerns for these business practices are different. A bundling discount introduces an added opportunity for a consumer to save money by purchasing multiple policies from the same company, while preserving the consumer's ability to shop for a better price or coverage by purchasing separate policies from unrelated companies. Tying achieves the opposite: a consumer who chooses, for example, a homeowners policy from a company engaging in tying then loses the ability to shop for an auto policy from another company. By purchasing or renewing a tied homeowners policy, the consumer's marketplace options for auto insurance are reduced from many to just one.

Proposed new §21.1008 is necessary to protect consumers from being unfairly pressured or compelled to purchase multiple products from one source instead of being able to choose the insurance coverage they want from any source they want. Usually, consumers must buy insurance to get a home loan or to comply with Texas motorist laws. Because consumers must have home and auto insurance, it underscores the importance of protecting their ability to freely shop for each policy. Tying arrangements can also pressure consumers to purchase unwanted coverage when they need or want only one policy and not the other tied to it. For example, a consumer who cannot drive or does not own a vehicle could be pressured to purchase an unwanted auto policy in order to purchase the homeowners policy the consumer prefers.

Prohibiting the tying of personal auto and residential property policies will also help prevent unfair competition among insurance companies and agents. Tying may give a company an unfair advantage by leveraging sales of one product to require sales of an unrelated product. This can make it difficult for new or rival companies to obtain sales. For example, if a company requires its homeowners policyholders to purchase auto policies from it, other companies could not compete for the personal auto business unless a consumer also chooses to switch the consumer's home insurance. Also, some companies cannot sell both residential property and personal auto insurance. For example, farm mutual insurance companies can write residential property insurance but are prohibited from writing personal automobile insurance.

The rule does not apply to all insurance products. The rule does not prohibit insurers tying commercial insurance products. It also does not prohibit tying products that supplement underlying coverage, such as personal umbrella or excess insurance policies which are often designed to work in tandem with an underlying homeowners or personal auto policy by extending liability coverage beyond the limits of the underlying policy. The rule's prohibition focuses on the tying of policies that provide coverage for two separate risks: the risk of damage to a person's home and belongings versus a person's risk as a driver and vehicle owner. While residential property owners frequently also need automobile coverage, it is not fair for an insurer or agent to refuse to sell one kind of coverage unless the consumer also purchases insurance from the insurer or agent for a fundamentally unrelated risk.

Subsection (a) of proposed new §21.1008 provides the purpose of the section--to protect consumers from being forced to purchase a product they do not want. The subsection also clarifies that it applies to any step of the purchasing process, including policy delivery, issuance, and renewal.

Subsection (b) of proposed new §21.1008 provides definitions for the section. The definition of "person" comes from Insurance Code §541.002(2), which is a wide-reaching definition, making the chapter and this rule applicable to any individual or other legal entity engaged in the business of insurance. The prohibition addresses both an insurer's underwriting practices and an insurer's or agent's sales practices. In addition to the broad definition, other sections in the Insurance Code affirm the applicability of Insurance Code Chapter 541 to various insurance entities. For example, Insurance Code §911.001 affirms applicability to farm mutual insurance companies; Insurance Code §912.002 affirms applicability to county mutual insurance companies; and Insurance Code §981.073 affirms applicability to surplus lines insurance. The definitions of "personal automobile insurance," "residential property insurance," and "underwriting guideline" come from Insurance Code §38.002, which relates to underwriting guidelines for personal automobile and residential property insurance policies. To avoid confusion and help ensure that protection is extended to farms and ranches, the definition for "residential property insurance" clarifies that this rule also includes farm and ranch insurance and farm and ranch owners insurance.

Subsection (c) of proposed new §21.1008 sets out the prohibition against certain tying requirements. It identifies tying that occurs through either a purchase requirement or an underwriting guideline as an unfair trade practice under Insurance Code Chapter 541. It limits the rule's prohibition to tying the purchase of a residential property insurance policy and a personal automobile insurance policy from a specific person. Tying arrangements for other types of insurance may be contrary to statute or rule and require a fact-based determination for each specific situation.

FISCAL NOTE AND LOCAL EMPLOYMENT IMPACT STATEMENT. David Muckerheide, assistant director of the Property and Casualty Lines Office, has determined that during each year of the first five years the proposed new section is in effect, there will be no measurable fiscal impact on state and local governments as a result of enforcing or administering the new section, other than that imposed by statute. Mr. Muckerheide made this determination because the proposed new section does not add to or decrease state revenues or expenditures, and because local governments are not involved in enforcing or complying with the proposed new section.

Mr. Muckerheide does not anticipate a measurable effect on local employment or the local economy as a result of this proposal.

PUBLIC BENEFIT AND COST NOTE. For each year of the first five years the proposed new section is in effect, Mr. Muckerheide expects that administering it will have the public benefit of ensuring that TDI is (1) implementing Insurance Code §541.003, (2) helping insurers comply with Insurance Code Chapter 541, (3) ensuring fair competition in the insurance industry, and (4) protecting the fair treatment of consumers.

Mr. Muckerheide expects that the proposed new section will increase the cost of compliance with Insurance Code Chapter 541 for persons engaged in tying personal automobile and residential property insurance. TDI is currently aware of only one company currently engaged in the type of tying this rule addresses. Companies that engage in tying will need to revise their underwriting guidelines and file them with TDI to comply with the rule. The cost to comply will vary depending on insurers' operations. Companies can still offer actuarially justified discounts for optional bundled policies.

While it is not feasible to determine the actual time required or the cost of employees needed to comply with the requirements, Mr. Muckerheide estimates that updating underwriting guidelines and filing them with TDI would take a range of one to five hours to complete and would likely require both software programming and clerical staff. According to the May 2023 Bureau of Labor Statistics Occupation and Employment Wage Statistics at www.bls.gov/oes/current/oes_nat.htm, the national mean hourly wage for the "Software and Web Developers, Programmers, and Testers" classification is $62.74, and the national mean hourly wage for the "Secretaries and Administrative Assistants, Except Legal, Medical, and Executive" classification is $21.87.

Any costs associated with this proposed new section are costs that are necessary to implement statute under Government Code §2001.0045(c)(9).

ECONOMIC IMPACT STATEMENT AND REGULATORY FLEXIBILITY ANALYSIS. TDI has determined that the proposed new section will not have an adverse economic effect on small or micro businesses, or on rural communities. The proposed new section might have a favorable effect on small and microbusinesses by eliminating tying arrangements that could unfairly constrict the market. Insurance companies or agents that are small businesses focused on selling only automobile insurance would not lose potential market share because a tying arrangement requires potential clients to purchase automobile coverage from a competitor. The same is true for insurance companies or agents that are small businesses focused on selling only residential property insurance. As a result, and in accordance with Government Code §2006.002(c), TDI is not required to prepare a regulatory flexibility analysis.

EXAMINATION OF COSTS UNDER GOVERNMENT CODE. §2001.0045. TDI has determined that this proposal does impose a cost on regulated persons engaged in tying personal automobile and residential property insurance. However, no additional rule amendments are required under Government Code §2001.0045 because the proposed new section is necessary to (1) implement legislation; and (2) protect the health, safety, and welfare of the residents of this state.

Insurance Code Chapter 541 repeatedly charges the commissioner to adopt and enforce rules that establish what actions constitute a violation of the chapter; *see* Insurance Code §§541.107, 541.201, 541.204, 541.301, 541.351, 541.352, and 541.401. The requirement that the commissioner identify specific unfair acts or practices that are putting the Texas market or consumers at risk is an ongoing duty under Chapter 541 and is necessary to accomplish the purpose of the chapter. The proposed new section is also necessary to protect the health, safety, and welfare of the residents of this state, as addressed by Government Code §2001.0045(c)(6), because prospective consumers would be otherwise subject to unfair trade practices by being compelled to purchase a product they do not want and hindering their ability to shop the market.

GOVERNMENT GROWTH IMPACT STATEMENT. TDI has determined that for each year of the first five years that the proposed new section is in effect, the proposed rule:

- will not create or eliminate a government program;

- will not require the creation of new employee positions or the elimination of existing employee positions;

- will not require an increase or decrease in future legislative appropriations to the agency;

- will not require an increase or decrease in fees paid to the agency;

- will create a new regulation;

- will not expand, limit, or repeal an existing regulation;

- will increase the number of individuals subject to the rule's applicability; and

- will not positively or adversely affect the Texas economy.

The proposed new section will identify a new act or practice as unfair under Insurance Code Chapter 541.

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

REQUEST FOR PUBLIC COMMENT. TDI will consider any written comments on the proposal that are received by TDI no later than 5:00 p.m., central time, on March 24, 2025. Send your comments to ChiefClerk@tdi.texas.gov or to the Office of the Chief Clerk, MC: GC-CCO, Texas Department of Insurance, P.O. Box 12030, Austin, Texas 78711-2030.

The commissioner of insurance will also consider written and oral comments on the proposal in a public hearing under Docket No. 2852 at 10:00 a.m. central time, on March 10, 2025, in Room 2.035 of the Barbara Jordan State Office Building, 1601 Congress Avenue, Austin, Texas 78701.

STATUTORY AUTHORITY. TDI proposes new §21.1008 under Insurance Code §541.401 and §36.001.

Insurance Code §541.401 provides that the commissioner may adopt and enforce reasonable rules the commissioner determines necessary to accomplish the purposes of Insurance Code Chapter 541.

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

CROSS-REFERENCE TO STATUTE. Proposed new §21.1008 implements Insurance Code §§31.002(4) and (5), 541.001, 541.003, 541.008, and 541.401.

§21.1008. Prohibited Tying Requirements.

(a) Purpose. The purpose of this section is to protect purchasers of either a personal automobile insurance policy or a residential property insurance policy from being required to purchase a policy of the other type as a condition of policy delivery, issuance, or renewal.

(b) Definitions. The following words and terms, when used in this section, have the following meanings:

(1) Person--As defined in Insurance Code §541.002(2), concerning Definitions.

(2) Personal automobile insurance--As defined in Insurance Code §38.002(a), concerning Underwriting Guidelines for Personal Automobile and Residential Property Insurance; Filing; Confidentiality.

(3) Residential property insurance--As defined in Insurance Code §38.002(a), but also includes farm and ranch insurance and farm and ranch owners insurance.

(4) Underwriting guideline--As defined in Insurance Code §38.002(a).

(c) Prohibited tying requirements. It is an unfair trade practice in violation of Insurance Code Chapter 541, concerning Unfair Methods of Competition and Unfair or Deceptive Acts or Practices, for a person to make the purchase of or use an underwriting guideline that makes the purchase of:

(1) a residential property insurance policy contingent on the purchase of a personal automobile insurance policy from any specific person; or

(2) a personal automobile insurance policy contingent on the purchase of a residential property insurance policy from any specific person.

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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Jessica Barta
General Counsel
Texas Department of Insurance
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TITLE 31. NATURAL RESOURCES AND CONSERVATION

PART 2. TEXAS PARKS AND WILDLIFE DEPARTMENT

CHAPTER 53. FINANCE

The Texas Parks and Wildlife Department proposes amendments to 31 TAC §§53.1 - 53.6, concerning Fees, §53.18, concerning License Issuance Procedures, Fees, Possession, and Exemption Rules - Provisions for Digital Products, and §53.60, concerning Stamps. The amendments would, in conjunction with other proposed rules affecting 31 TAC Chapter 57, Subchapter N, concerning the Statewide Recreational and Commercial Fishing Proclamations, and Chapter 65, Subchapter A, concerning the Statewide Hunting Proclamation, published elsewhere in this issue of the *Texas Register*, expand the current provisions regarding the issuance and use of digital products to include and apply to all recreational hunting, fishing, and combination hunting and fishing licenses and stamp endorsements currently issued by the department directly to hunters and anglers, as well as the Annual Public Hunting Permit, Limited Use Permit, Harvest Information Program certification, Hunter Education Deferral Option, federal sandhill crane permit, and controlled exotic snake permit.

The 87th Texas Legislature (2021) enacted House Bill (H.B.) 3081, which authorized the commission to develop and implement a program for the issuance of digital tags for animals, including birds, to holders of hunting licenses authorizing the taking of those animals. The department accordingly initiated a pilot program in 2022 to determine the public receptivity to and logistical feasibility of the concept of digital licenses, stamp endorsements, and tags for hunting and fishing, which resulted in the creation of digital versions of the super combination hunting and "all water" fishing license and the lifetime resident super combination hunting and "all water" fishing package (47 TexReg 88). In 2022, after an analysis of customer purchasing behavior with respect to digital licenses and products, the department determined that it was appropriate to offer a digital version of the youth hunting license, the lifetime resident hunting license, and the lifetime fishing license for the license year beginning September 1, 2023, as well as the exempt angler red drum tag, which allows persons who are exempt from fishing license and stamp endorsement requirements to harvest red drum. The department is now confident, based on these pilot programs, that all recreational hunting and fishing licenses, stamp endorsements, tags, and selected permits that are sold directly to users can be made available to the public as digital products, which is the purpose of this proposed rulemaking.

The proposed amendments to §53.1, concerning Applicability, would add definitions for "digital product," "electronic acquisition - electronically," "physical product," and "virtual documentation" in order to provide precise and unambiguous meanings for those terms as they are used in the proposed rules.

The proposed amendments to §53.2, concerning License Issuance Procedures, Fees, Possession, and Exemption Rules, §53.3, concerning Combination Hunting and Fishing License Packages, §53.4, concerning Lifetime Licenses, §53.5, concerning Recreational Hunting Licenses, Stamps, and Tags, and §53.6, concerning Recreational Fishing Licenses, Stamps, and Tags, would make conforming changes necessary to comport with the proposed amendment to §53.18, concerning License Issuance Procedures, Fees, Possession, and Exemption Rules - Provisions for Digital Products, which would be retitled "Digital Products," and become the controlling authority for all digital products offered by the department.

The proposed amendment to §53.18, concerning License Issuing Procedures, Fees, Possession, and Exemption Rules - Provisions for Digital Products, would retitle the section and make the provisions of the section applicable to all recreational hunting and fishing licenses, stamp endorsements, tags sold directly to the public, as well as the selected permits mentioned previously in this preamble. The effect of the proposed amendment would be to make digital versions of all recreational hunting and fishing licenses, stamp endorsements, tags, and select permits currently directly available to the public (in addition to the traditional versions of those products).

The proposed amendment to §53.60, concerning Stamps, also would make conforming changes necessary to comport with the proposed amendment to §53.18.

Chris Cerny, Business Analyst, has determined that for each of the first five years that the rules as proposed are in effect, there will be minimal fiscal implications for the department, if any, and those fiscal implications will be positive.

There will be no implications for other units of state or local governments as a result of administering or enforcing the rules.

Mr. Cerny also has determined that for each of the first five years that the rules as proposed are in effect, the public benefit anticipated as a result of enforcing or administering the proposed rules will be the provision of additional licensing options for the convenience and enjoyment of the public.

Under the provisions of Government Code, Chapter 2006, a state agency must prepare an economic impact statement and a regulatory flexibility analysis for a rule that may have an adverse economic effect on small businesses, micro-businesses, or rural communities. As required by Government Code, §2006.002(g), the Office of the Attorney General has prepared guidelines to assist state agencies in determining a proposed rule's potential adverse economic impacts to small businesses, micro-businesses, or rural communities. Those guidelines state that an agency need only consider a proposed rule's "direct adverse economic impacts" to small businesses and micro-businesses to determine if any further analysis is required. For that purpose,

the department considers "direct economic impact" to mean a requirement that would directly impose recordkeeping or reporting requirements; impose taxes or fees; result in lost sales or profits; adversely affect market competition; or require the purchase or modification of equipment or services.

The department has determined that the proposed rules will not result in direct adverse impacts on small businesses, micro-businesses, or rural communities because the proposed rules regulate various aspects of recreational license privileges that allow individual persons to pursue and harvest public wildlife resources in this state and therefore do not directly affect small businesses, micro-businesses, or rural communities. Therefore, neither the economic impact statement nor the regulatory flexibility analysis described in Government Code, Chapter 2006, is required.

The department has not drafted a local employment impact statement under the Administrative Procedures Act, §2001.022, as the agency has determined that the rules as proposed will not impact local economies.

The department has determined that Government Code, §2001.0225 (Regulatory Analysis of Major Environmental Rules), does not apply to the proposed rules.

The department has determined that there will not be a taking of private real property, as defined by Government Code, Chapter 2007, as a result of the proposed rules.

In compliance with the requirements of Government Code, §2001.0221, the department has prepared the following Government Growth Impact Statement (GGIS). The rules as proposed, if adopted, will:

(1) neither create nor eliminate a government program; not result in an increase or decrease in the number of full-time equivalent employee needs; not result in a need for additional General Revenue funding; not affect the amount of any fee; not create, repeal, or limit a regulation; expand a regulation (by making all recreational hunting and fishing licenses and certain permits available as digital license products); neither increase nor decrease the number of individuals subject to regulation; and not positively or adversely affect the state's economy.

Comments on the proposal may be submitted to Chris Cerny at (512) 389-4594, e-mail: chris.cerny@tpwd.texas.gov. Comments also may be submitted via the department's website at http://www.tpwd.texas.gov/business/feedback/public_comment/.

SUBCHAPTER A. FEES

DIVISION 1. LICENSE, PERMIT, AND BOAT AND MOTOR FEES

31 TAC §§53.1 - 53.6, 53.18

The amendments are proposed under the authority of Parks and Wildlife Code, §42.010, which requires the department to prescribe the form and issuance of hunting licenses authorized under Parks and Wildlife Code, Chapter 42; §42.0101, which authorizes the commission to promulgate rules for the issuance of digital tags for animals, including birds, to holders of hunting licenses authorizing the taking of those animals, including rules allowing a person using a digital tag to create a digital record at the time of the taking of an animal that includes information required by the department as soon as possible after the taking of the animal and requiring a person using a digital tag to retain in the person's possession documentation of a required digital record at all times before the carcass is finally processed; §42.0177, which authorizes the commission to modify or eliminate the tagging, carcass, final destination, and final processing requirements of Chapter 42; §42.006, which authorizes the commission to prescribe requirements relating to possessing a license issued under Chapter 42 by rule; §46.0085, which authorizes the department to issue tags for finfish species allowed by law to be taken during each year or season from coastal waters of the state to holders of licenses authorizing the taking of finfish species; §46.0086, which authorizes the commission to prescribe tagging requirements for the take of finfish; §50.004, which requires the department to issue and prescribe the form and manner of issuance for combination hunting and fishing licenses, including identification and compliance requirements; §61.052, which requires the commission to regulate the periods of time when it is lawful to hunt, take, or possess game animals, game birds, or aquatic animal life in this state; and §61.054 which requires the commission to specify the means, methods, and places in which it is lawful to hunt, take, or possess game animals, game birds, or aquatic animal life in this state; the species, quantity, age or size, and, to the extent possible, the sex of the game animals, game birds, or aquatic animal life authorized to be hunted, taken, or possessed; and the region, county, area, body of water, or portion of a county where game animals, game birds, or aquatic animal life may be hunted, taken, or possessed.

The proposed amendments affect Parks and Wildlife Code, Chapters 42, 46, 50, and 61.

§53.1. Applicability; Definitions.

(a) Except for the fees established in Chapter 59 of this title (relating to Parks) and Chapter 69, Subchapter H, of this title (relating to Issuance of Marl, Sand, and Gravel Permits), the fees established by this chapter prevail over all other chapters in this title.

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

(1) Digital product (digital license, digital stamp endorsement, digital tag, digital permit)--A license, stamp endorsement, tag, or permit issued by the department that is not a physical license, physical stamp endorsement, physical tag, or physical permit but serves as virtual documentation of a person's hunting and/or fishing privileges and compliance with the applicable license and permit requirements of the Parks and Wildlife Code and rules of the commission.

(2) Electronic acquisition (electronically)--Acquisition of a license, stamp endorsement, tag, or permit, issued in either digital or physical form, from the department by phone or online.

(3) Physical product (physical license, physical stamp endorsement, physical tag, or physical permit)--A tangible, material license, stamp endorsement, tag, or permit issued by the department that serves as tangible documentation of a person's specific hunting and/or fishing privileges and compliance with the applicable license and permit requirements of the Parks and Wildlife Code and the rules of the commission.

(4) Virtual documentation--An electronic record obtained from and maintained by the department indicating the purchase, possession, or acquisition of a digital product.

§53.2. License Issuance Procedures, Fees, Possession, and Exemption Rules.

(a) Hunting license [~~possession~~].

(1) (No change.)

(2) A person may hunt in this state without having a valid physical hunting license in immediate possession if that person has acquired a license electronically and has either:

(A) a receipt, notification, or application data from the department on a smart phone, computer, tablet, or similar device indicating acquisition of an appropriate digital product identified in §53.18 of this title (relating to Digital Products); [a digital license described in §53.3(a)(12) of this title (relating to Combination Hunting and Fishing License Packages) or §53.4(a)(1) of this title (relating to Lifetime Licenses);] or

(B) (No change.)

(3) - (4) (No change.)

(b) Fishing license; Tags [possession].

(1) A person may fish in this state without having a valid physical fishing license in immediate possession if that person:

(A) (No change.)

(B) has acquired a license electronically and has either:

(i) a receipt, notification, or application data from the department on a smart phone, computer, tablet, or similar device indicating acquisition of a digital product identified in §53.18 of this title [license described in §53.3(a)(12) of this title or §53.4(a)(1) of this title]; or

(ii) (No change.)

(2) No person may catch and retain a red drum or spotted seatrout exceeding the maximum length limit established in Chapter 57, Subchapter N, Division 2, of this title (relating to Statewide Recreational Fishing Proclamation [over 28 inches in length] in the coastal waters of this state without having a valid physical fishing license, saltwater sportfishing stamp (unless exempt), and valid appropriate (red drum or spotted seatrout) tag in immediate possession, unless the person has purchased a valid digital product identified in §53.18 of this title [license described in §53.3(a)(12) of this title or a valid license with digital tags under §53.4(a)(1) of this title].

[(3) No person may catch and retain a spotted seatrout 28 inches or greater in length in the coastal waters of this state without having a valid fishing license, saltwater sportfishing stamp (unless exempt), and valid Spotted Seatrout tag in immediate possession, unless the person has purchased a valid digital license described in §53.3(a)(12) of this title or a valid license with digital tags under §53.4(a)(1) of this title.]

(c) Issuance of licenses and stamp endorsements electronically (on-line or by telephone).

(1) - (2) (No change.)

(3) The fees established by this subsection also apply to the electronic acquisition of a digital product [license] identified in §53.18 of this title [§53.3(a)(12) of this title or §53.4(a)(1)] of this title.

(d) - (g) (No change.)

(h) A person who has purchased a valid physical hunting, fishing, or combination hunting and fishing license product but is not in physical possession of that physical license product [license] in any circumstance for which physical possession of the license product [the license] is required may use a wireless communications device (laptop, cellphone, smart phone, electronic tablet, phablet, or similar device) to satisfy applicable license possession requirements.

(1) - (3) (No change.)

§53.3. Combination Hunting and Fishing License Packages.

(a) Combination hunting and fishing license packages may be priced at an amount less than the sum of the license and stamp prices of the individual licenses and stamps included in the package.

(1) - (11) (No change.)

[(12) Digital super combination hunting and "all water" fishing license package. The licenses listed in paragraphs (7) and (8) of this subsection are available in a digital version that does not include the license log or the physical license tags found on the physical license.]

[(A) The fee for a digital license identified in this paragraph shall be the same as the fee specified for that license in paragraphs (7) and (8) of this section.]

[(B) A person who acquires a digital license is ineligible to acquire any other form of recreational hunting or fishing license in the same license year.]

[(C) The digital licenses identified in this paragraph are available only through the department's website at www.tpwd.texas.gov.]

[(D) The provisions of §65.8 of this title (relating to Alternative Licensing System) do not apply to a digital license.]

(12) [(13)] Replacement combination or replacement super combination packages--$10 except for a replacement disabled veteran super combination hunting and "all water" fishing package or a Texas resident active-duty [active duty] military super combination hunting and "all water" fishing package, which shall be replaced at no charge.

(b) (No change.)

§53.4. Lifetime Licenses.

(a) - (c) (No change.)

[(d) The licenses listed in this section are available with a digital tag option that does not require the license log or the physical license tags found on the physical license.]

[(1) The digital tag option is available beginning the year after the year of purchase of the license (and each year thereafter); and]

[(2) the provisions of §53.3(a)(12)(B) - (D) of this title (relating to Combination Hunting and Fishing License Packages) apply.]

§53.5. Recreational Hunting Licenses, Stamps, and Tags.

(a) Hunting Licenses:

(1) - (2) (No change.)

(3) youth hunting--$7.

[(A) Valid for any person under 17 years of age on the date of license purchase.]

[(B) This license is available in a digital version that does not include the license log or the physical license tags found on the physical license.]

(4) - (9) (No change.)

(b) - (d) (No change.)

§53.6. Recreational Fishing Licenses, Stamps, and Tags.

(a) - (d) (No change.)

(e) Fishing tags:

(1) exempt angler red drum tag (provides a red drum tag for persons that are exempt by statute or rule from the purchase of a resident or non-resident fishing license of any type or duration)--$3;

[(A) Provides a red drum tag for persons that are exempt from the purchase of a resident or non-resident fishing license of any type or duration.]

[(B) This tag is available in a digital version. At the time of execution, the user must be in possession of a smart phone, computer, tablet, or similar device indicating acquisition of the digital tag.]

(2) bonus red drum tag (provides a second red drum tag to persons who [that] have previously received a red drum tag)--$3. [This tag is available in a digital version. At the time of execution, the user must be in possession of a smart phone, computer, tablet, or similar device indicating acquisition of the digital tag;]

(3) exempt angler spotted seatrout tag (provides a spotted seatrout tag for persons who are exempt by statute or rule from the purchase of a resident or non-resident fishing license of any type or duration)--$3;

[(A) provides a spotted seatrout tag for persons that are exempt from the purchase of a resident or non-resident fishing license of any type or duration.]

[(B) this tag is available in a digital version. At the time of execution, the user must be in possession of a smart phone, computer, tablet, or similar device indicating acquisition of the digital tag.]

(4) bonus spotted seatrout tag ([-] provides a second spotted seatrout tag to persons who [that] have previously received a spotted seatrout tag)--$3. [This tag is available in a digital version. At the time of execution, the user must be in possession of a smart phone, computer, tablet, or similar device indicating acquisition of the digital tag;]

(5) - (6) (No change.)

§53.18. [License Issuance Procedures, Fees, Possession, and Exemption Rules - Provisions for] Digital Products.

(a) Digital Products. [The provisions of this section are in addition to the provisions of §53.2 of this title (relating to License Issuance Procedures, Fees, Possession, and Exemption Rules) and to the extent that any provision of this section conflicts with the provisions of §53.2 of this title, this section controls].

(1) The licenses, stamp endorsements, and tags listed in §§53.3, 53.4, 53.5(a) and (c), and 53.6(a) - (c) and (e)(1) - (4) of this title (relating to Combination Hunting and Fishing License Packages; Lifetime Licenses; Recreational Hunting Licenses, Stamps, and Tags; and Recreational Fishing Licenses, Stamps, and Tags) are available as a digital product. Digital licenses do not include the license log or the physical license tags found on the traditional physical license.

(2) In addition to the license products identified in paragraph (1) of this subsection, the following items are available as digital products:

(A) the public hunting permits identified in §53.10(a)(1) and (3) of this title (relating to Public Hunting Permits and Fees);

(B) the federal sandhill crane permit required by §65.318 of this title (relating to Sandhill Crane);

(C) the hunter education deferral option established in §51.80 of this title (relating to Mandatory Hunter Education);

(D) the reptile and amphibian stamp required by Parks and Wildlife Code, Chapter 43, Subchapter W; and

(E) the recreational controlled exotic snake permit required by §55.652 of this title (relating to Controlled Exotic Snakes).

(b) General Provisions.

(1) To the extent that any provision of this section conflicts with the provisions of §53.2 of this title, this section controls.

(2) A person who acquires a digital license is ineligible to acquire any other form of recreational hunting or fishing license in the same license year.

(3) The fees established in this division also apply to the issuance of the digital products identified in this section.

(4) The digital products associated with items enumerated in §53.4 of this title are available beginning the year after the year of purchase of the license (and each year thereafter).

(5) A person who has acquired a digital product may engage in an activity permitted or authorized by the digital product, provided the person Hunting license possession. A person may hunt in this state without having a valid physical hunting license in immediate possession if that person has acquired a license electronically and] has a receipt, notification, or application data from the department on a smart phone, computer, tablet, or similar device indicating acquisition of the appropriate digital product. [a digital license described in §53.3(a)(12) of this title (relating to Combination Hunting and Fishing License Packages), §53.4 of this title (relating to Lifetime Licenses), or §53.5(a)(3) of this title (relating to Recreational Hunting Licenses, Stamps, and Tags).]

(6) The provisions of §65.8 of this title (relating to Alternative Licensing System) do not apply to a digital license.

(7) Because a digital product does not physically exist, the provisions of this subchapter that apply to replacement licenses do not apply to digital products.

(c) Fishing [license possession].

[(1)] A person may fish in this state without having an appropriate, [a] valid physical fishing license product in immediate possession if that person has acquired a license electronically and has a receipt, notification, or application data from the department on a smart phone, computer, tablet, or similar device indicating acquisition of an appropriate [a] digital product [license described in §53.3(a)(12) of this title or §53.4 of this title].

[(2) A person may catch and retain a red drum over 28 inches in length in the coastal waters of this state without having a valid fishing license, saltwater sportfishing stamp, and valid red drum tag in immediate possession, if the person has:]

[(A) obtained a valid digital exempt angler red drum tag; or]

[(B) purchased a valid digital license described in §53.3(a)(12) of this title or a valid license with digital tags under 53.4 of this title.]

[(3) A person may catch and retain a spotted seatrout 28 inches or greater in length in the coastal waters of this state without having a valid fishing license, saltwater sportfishing stamp, and valid spotted seatrout tag in immediate possession, if the person has:]

[(A) obtained a valid digital exempt angler spotted seatrout tag; or]

[(B) purchased a valid digital license described in §53.3(a)(12) of this title or a valid license with digital tags under 53.4 of this title.]

(d) Fees. [Issuance of licenses, stamp endorsements, and tags electronically (on-line or by telephone).]

[(1) A person may acquire a tag electronically from the department by agreeing to pay a convenience fee of up to $5 in addition to the normal tag fee, if a fee is required. This fee shall not be charged if the tag is acquired in the same transaction with a license.]

[(2)] The fees established by this subsection apply to the electronic acquisition of a digital product [license, stamp endorsement, or tag] identified in subsection (a) of this section [§53.3(a)(12) of this title, 53.4 of this title, §53.5(a)(3) of this title, or §53.6 of this title (relating to Recreational Fishing Licenses, Stamps, and Tags)].

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 February 10, 2025.

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James Murphy
General Counsel
Texas Parks and Wildlife Department
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For further information, please call: (512) 389-4775

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SUBCHAPTER B. STAMPS

31 TAC §53.60

The amendment is proposed under the authority of Parks and Wildlife Code, §42.010, which requires the department to prescribe the form and issuance of hunting licenses authorized under Parks and Wildlife Code, Chapter 42; §42.0101, which authorizes the commission to promulgate rules for the issuance of digital tags for animals, including birds, to holders of hunting licenses authorizing the taking of those animals, including rules allowing a person using a digital tag to create a digital record at the time of the taking of an animal that includes information required by the department as soon as possible after the taking of the animal and requiring a person using a digital tag to retain in the person's possession documentation of a required digital record at all times before the carcass is finally processed; §42.0177, which authorizes the commission to modify or eliminate the tagging, carcass, final destination, and final processing requirements of Chapter 42; §42.006, which authorizes the commission to prescribe requirements relating to possessing a license issued under Chapter 42 by rule; §46.0085, which authorizes the department to issue tags for finfish species allowed by law to be taken during each year or season from coastal waters of the state to holders of licenses authorizing the taking of finfish species; §46.0086, which authorizes the commission to prescribe tagging requirements for the take of finfish; §50.004, which requires the department to issue and prescribe the form and manner of issuance for combination hunting and fishing licenses, including identification and compliance requirements; §61.052, which requires the commission to regulate the periods of time when it is lawful to hunt, take, or possess game animals, game birds, or aquatic animal life in this state; and §61.054 which requires the commission to specify the means, methods, and places in which it is lawful to hunt, take, or possess game animals, game birds, or aquatic animal life in this state; the species, quantity, age or size, and, to the extent possible, the sex of the game animals, game birds, or aquatic animal life authorized to be hunted, taken, or possessed; and the region, county, area, body of water, or portion of a county where game animals, game birds, or aquatic animal life may be hunted, taken, or possessed.

The proposed amendments affect Parks and Wildlife Code, Chapters 42, 46, 50, and 61.

§53.60. Stamps.

(a) Stamp Form, Design and Manner of Issuance.

(1) (No change.)

(2) A digital combination license or combination license package issued under the provisions of §53.18 of this title (relating to Digital Products [§53.3(a)(12) of this title (relating to Combination Hunting and Fishing License Packages)] includes all required endorsements.

(b) Stamp Purchase Identification and Possession Requirements.

(1) A person may hunt without a required state hunting stamp endorsement in immediate possession if the person:

(A) possesses a valid digital product [license] issued under the provisions of §53.18 of this title [§53.3(a)(12) of this title, a valid license with digital tags under §53.4 of this title (relating to Lifetime Licenses) or §53.5(a)(3) of this title (relating to Recreational Hunting Licenses, Stamps, and Tags]; or

(B) has acquired a stamp endorsement electronically and has a valid authorization number in possession while awaiting fulfilment of the physical tag. Authorization numbers shall only be valid for 20 days from purchase date.

(2) A person may fish without a required fishing stamp endorsement in immediate possession if the person:

(A) possesses a valid digital product [license] issued under the provisions of §53.18 of this title §53.3(a)(12) of this title or a valid license with digital tags under §53.4 of this title]; or

(B) has acquired a stamp endorsement electronically and has a valid authorization number in possession while awaiting fulfilment of the physical tag. Authorization numbers shall only be valid for 20 days from purchase date.

(c) - (e) (No change.)

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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James Murphy
General Counsel
Texas Parks and Wildlife Department
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CHAPTER 57. FISHERIES

The Texas Parks and Wildlife Department proposes amendments to 31 TAC §§57.156, 57.252, and 57.253, concerning Fisheries.

The proposed amendment to §57.156, concerning Definitions, would remove a reference to a publication that no longer is ap-

plicable to the rule. The Texas Parks and Wildlife Commission finds that removing the reference is necessary to eliminate possible confusion.

The proposed amendment to §57.252, concerning General Provisions, would, for the sake of clarity, add a provision repeating the statutory prohibition (Parks and Wildlife Code, §66.015) of the act of introducing any species of fish, shellfish, or aquatic plant into the public water of the state without a permit issued by the department.

The proposed amendment to §57.253, concerning Permit Application, would eliminate subsection (c)(2)(B)(i), which is no longer necessary because the Texas Department of Agriculture no longer regulates aquaculture.

The proposed amendments are a result of the department's review of its regulations under the provisions of Government Code, §2001.039, which requires each state agency to review each of its regulations no less frequently than every four years and to re-adopt, adopt with changes, or repeal each rule as a result of the review.

Robert Macdonald, Regulations Coordinator, has determined that for each of the first five years that the rules as proposed are in effect, there will be no fiscal implications to state or local governments as a result of administering or enforcing the rules.

Mr. Macdonald also has determined that for each of the first five years that the rules as proposed are in effect, the public benefit anticipated as a result of enforcing or administering the proposed rules will be accurate department regulations.

There will be no adverse economic effect on persons required to comply with the rules as proposed, as the rules apply only to internal department administrative processes.

Under the provisions of Government Code, Chapter 2006, a state agency must prepare an economic impact statement and a regulatory flexibility analysis for a rule that may have an adverse economic effect on small businesses, micro-businesses, or rural communities. As required by Government Code, §2006.002(g), the Office of the Attorney General has prepared guidelines to assist state agencies in determining a proposed rule's potential adverse economic impact on small and microbusinesses and rural communities. Those guidelines state that an agency need only consider a proposed rule's direct adverse economic impacts to determine if any further analysis is required. The department considers "direct economic impact" to mean a requirement that would directly impose recordkeeping or reporting requirements; impose taxes or fees; result in lost sales or profits; adversely affect market competition; or require the purchase or modification of equipment or services.

The department has determined that the proposed rules would result in no direct economic effect on any small businesses, micro-businesses, or rural community, as the rules apply only to internal department administrative processes and not to any business or person. Therefore, neither the economic impact statement nor the regulatory flexibility analysis described in Government Code, Chapter 2006, is required.

The department has not drafted a local employment impact statement under the Administrative Procedures Act, §2001.022, as the agency has determined that the rules as proposed will not impact local economies.

The department has determined that Government Code, §2001.0225 (Regulatory Analysis of Major Environmental Rules), does not apply to the proposed rules.

The department has determined that there will not be a taking of private real property, as defined by Government Code, Chapter 2007, as a result of the proposed rules.

In compliance with the requirements of Government Code, §2001.0221, the department has prepared the following Government Growth Impact Statement (GGIS). The rules as proposed, if adopted, will not create nor eliminate a government program; not result in an increase or decrease in the number of full-time equivalent employee needs; not result in a need for additional General Revenue funding; not affect the amount of an existing fee; not create, expand, or repeal an existing regulation; not increase or decrease the number of individuals subject to regulation; and not positively or adversely affect the state's economy.

Comments on the proposed rules may be submitted to Robert Macdonald at (512) 389-4775, e-mail: robert.macdonald@tpwd.texas.gov. Comments also may be submitted via the department's website at http://www.tpwd.texas.gov/business/feedback/public_comment/.

SUBCHAPTER B. MUSSELS AND CLAMS

31 TAC §57.156

The amendment is proposed under Parks and Wildlife Code, §78.006, which authorizes the to regulate the taking, possession, purchase, and sale of mussels and clams.

The proposed amendment affects Parks and Wildlife Code, Chapter 11.

§57.156. Definitions.

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

(1) (No change.)

(2) Freshwater mussel--Bivalve mollusks of the family Unionidae [~~(collectively including Amblimidae and Margaritiferidae) as listed by the American Fisheries Society Special Publication 29~~].

(3) - (5) (No change.)

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 C. INTRODUCTION OF FISH, SHELLFISH AND AQUATIC PLANTS

31 TAC §57.252, §57.253

The amendment is proposed under the authority of Parks and Wildlife Code, §66.007, which requires the department to make rules to carry out the provisions of that section.

The proposed amendment affects Parks and Wildlife Code, Chapter 66.

§57.252. General Provisions.

(a) No person may place any species of fish, shellfish, or aquatic plant into the public water of the state without a permit issued by the department.

(b) [~~(a)~~] An offshore aquaculture permit under this subchapter may be issued to an individual, corporation, company, or other entity that meets all requirements of Texas law for transacting business in this state and the requirements of this subchapter applicable to offshore aquaculture permits.

(c) [~~(b)~~] A permit under this subchapter other than for an offshore aquaculture facility may be issued to a named individual only and not to a corporation, partnership, or other entity.

(d) [~~(c)~~] A permit issued under this subchapter shall not be sold or transferred except with the approval of the department.

(e) [~~(d)~~] Except as provided by the terms and conditions of the permit, a one-time introduction permit, for releases other than those made into an offshore aquaculture facility, is valid for 60 days from the date of issuance or until the permitted introduction has been completed, whichever comes first.

(f) [~~(e)~~] For offshore aquaculture facilities:

(1) - (7) (No change.)

(g) [~~(f)~~] A holder of an offshore aquaculture permit must:

(1) - (5) (No change.)

(h) [~~(g)~~] A permit is not required for any person, while fishing, to place goldfish (Carassius auratus), common carp (Cyprinus carpio), native shrimp, crabs, crawfish and nongame fish into public waters or to immediately release any fish that does not comply with size and bag limits for that species.

(i) [~~(h)~~] An employee of the department acting at the direction of the executive director is exempt from the permit requirements specified by these sections.

§57.253. Permit Application.

(a) - (b) (No change.)

(c) An application for an offshore aquaculture facility:

(1) (No change.)

(2) must include:

(A) (No change.)

(B) proof that the applicant has obtained:

~~(i)~~ ~~a valid license issued by the Texas Department of Agriculture to operate an aquaculture facility (Agriculture Code Chapter 134);~~]

(i) [~~(ii)~~] all applicable state and/or federal permits or authorizations relating to water quality standards;

(ii) [~~(iii)~~] all applicable state and federal permits, authorizations, or clearances related to navigational hazards; and

(iii) [~~(iv)~~] any approval or permit required by the General Land Office;

(C) - (G) (No change.)

(d) - (f) (No change.)

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 57. FISHERIES

The Texas Parks and Wildlife Department proposes the repeal of 31 TAC §57.984 and §57.985 and amendments to §57.981 and §57.992, concerning the Statewide Recreational and Commercial Fishing Proclamations.

The repeal of §57.984, concerning Special Provisions - Digital Exempt Angler Tags is necessary to comport current rules with proposed provisions published elsewhere in this issue that would make all recreational fishing license products (licenses, stamp endorsements, tags, and selected permits) available as digital products.

The proposed repeal of §57.985, concerning Spotted Seatrout-Special Provisions, is necessary to remove temporary interim provisions governing the take of spotted seatrout, adopted as a stand-alone section in 2024 to avoid conflict with other proposed rulemaking, in order to move them to §57.981, concerning Bag, Possession, and Length Limits, where they properly belong.

In February of 2021, Winter Storm Uri resulted in the largest freeze-related fish kill on the Texas Gulf coast since the 1980s, severely impacting spotted seatrout populations coastwide. In an effort to accelerate recovery of the spotted seatrout population, the department promulgated a series of rules that implemented reduced bag and "slot" (a mechanism to protect certain age classes) limits. Department monitoring has continuously indicated lower post-freeze catch rates (compared to the previous ten-year average), and the commission accordingly acted to implement continued measures to enhance and accelerate population recovery, adopting rules that reduced the bag limit and narrowed the slot limit for spotted seatrout. In January 2024, the commission directed staff to develop a mechanism to allow the retention of "oversized" fish (fish in excess of the maximum length established by rule) at a level not likely to compromise or defeat recovery measures, resulting in the adoption of §57.985, which also replaced the previous daily limit for the retention of oversized spotted seatrout with an annual limit.

The proposed amendment to §57.981, concerning Bag, Possession, and Length Limits, would incorporate the contents of current §57.985, concerning Spotted Seatrout - Special Provisions, for reasons discussed earlier in this preamble. The proposed repeal and amendment are not substantive, do not alter the applicability of the rules currently in force and effect, and serve only to consolidate all provisions governing spotted seatrout harvest in a single place. The proposed amendment also would make conforming changes to accommodate proposed amendments to

Chapter 53, concerning Finance, published elsewhere in this issue, that would provide for the issuance of all recreational fishing licenses, stamp endorsements, and tags as digital products. In 2021, the department launched a pilot program to determine the feasibility of implementing digital versions of physical licenses, tags, and permits. The results of the pilot program were favorable, and the department is therefore proceeding with respect to making all recreational fishing licenses, stamp endorsements, and tags available as digital products.

The proposed amendment to §57.992, concerning Bag, Possession, and Length Limits, would liberalize commercial harvest regulations for greater amberjack in Texas state waters by increasing the maximum length (currently 34 total inches) to match the current federal standard, which is 40 inches (total length). The amendment is intended to make commercial harvest regulations for greater amberjack consistent with federal regulations, which the department believes will prevent confusion and enhance compliance, administration, and enforcement.

Robert Macdonald, Regulations Coordinator, has determined that for each of the first five years that the rules as proposed are in effect, there will be no fiscal implications to state or local governments as a result of administering or enforcing the rules.

Mr. Macdonald also has determined that for each of the first five years that the rules as proposed are in effect, the public benefit anticipated as a result of enforcing or administering the proposed rules will be the dispensation of the agency's statutory duty to protect and conserve the resources of this state, the duty to equitably distribute opportunity for the enjoyment of those resources among the citizens, and the execution of the commission's policy to maximize recreational opportunity within the precepts of sound biological management practices.

There will be no adverse economic effect on persons required to comply with the rules as proposed.

Under the provisions of Government Code, Chapter 2006, a state agency must prepare an economic impact statement and a regulatory flexibility analysis for a rule that may have an adverse economic effect on small businesses, micro-businesses, or rural communities. As required by Government Code, §2006.002(g), the Office of the Attorney General has prepared guidelines to assist state agencies in determining a proposed rule's potential adverse economic impact on small and microbusinesses and rural communities. Those guidelines state that an agency need only consider a proposed rule's "direct adverse economic impacts" to determine if any further analysis is required. The department considers "direct economic impact" to mean a requirement that would directly impose recordkeeping or reporting requirements; impose taxes or fees; result in lost sales or profits; adversely affect market competition; or require the purchase or modification of equipment or services.

The department has determined that the proposed repeals and the proposed amendment to §57.982 regulate various aspects of recreational license privileges that allow individual persons to pursue and harvest wildlife resources in this state and therefore do not directly affect small businesses, micro-businesses, or rural communities. Therefore, neither the economic impact statement nor the regulatory flexibility analysis described in Government Code, Chapter 2006, is required. With respect to the proposed amendment to §57.992, which affects commercial fisheries, the rules are necessary to comport state rules with federal rules and affect conduct that would be unlawful under federal law without respect to state action. Therefore, neither the economic impact statement nor the regulatory flexibility analysis described in Government Code, Chapter 2006, is required.

The department has not drafted a local employment impact statement under the Administrative Procedures Act, §2001.022, as the agency has determined that the rules as proposed will not exert a direct economic impact on local economies.

The department has determined that Government Code, §2001.0225 (Regulatory Analysis of Major Environmental Rules), does not apply to the proposed rules.

The department has determined that there will not be a taking of private real property, as defined by Government Code, Chapter 2007, as a result of the proposed rules.

In compliance with the requirements of Government Code, §2001.0221, the department has prepared the following Government Growth Impact Statement (GGIS). The rules as proposed, if adopted, will: neither create nor eliminate a government program; not result in an increase or decrease in the number of full-time equivalent employee needs; not result in a need for additional General Revenue funding; not affect the amount of any fee; not create a new regulation, but modify existing regulations; will repeal an existing regulation, but will not limit an existing regulation; neither increase nor decrease the number of individuals subject to regulation; and not positively or adversely affect the state's economy.

Comments on the proposal may be submitted to Dakus Geeslin (Coastal Fisheries), at (512) 389-8734 (email: Dakus.Geeslin@tpwd.texas.gov). Comments also may be submitted via the department's website at http://www.tpwd.texas.gov/business/feedback/public_comment/.

SUBCHAPTER N. STATEWIDE RECREATIONAL AND COMMERCIAL FISHING PROCLAMATION

DIVISION 2. STATEWIDE RECREATIONAL FISHING PROCLAMATION

31 TAC §57.981

The amendment is proposed under the authority of Parks and Wildlife Code, Parks and Wildlife Code, §46.0085, which authorizes the department to issue tags for finfish species allowed by law to be taken during each year or season from coastal waters of the state to holders of licenses authorizing the taking of finfish species; §46.0086, which authorizes the commission to prescribe tagging requirements for the take of finfish; §50.004, which requires the department to issue and prescribe the form and manner of issuance for combination hunting and fishing licenses, including identification and compliance requirements; and Chapter 61, which requires the commission to regulate the periods of time when it is lawful to hunt, take, or possess game animals, game birds, or aquatic animal life in this state; the means, methods, and places in which it is lawful to hunt, take, or possess game animals, game birds, or aquatic animal life in this state; the species, quantity, age or size, and, to the extent possible, the sex of the game animals, game birds, or aquatic animal life authorized to be hunted, taken, or possessed; and the region, county, area, body of water, or portion of a county where game animals, game birds, or aquatic animal life may be hunted, taken, or possessed.

The proposed amendment affects Parks and Wildlife Code, Chapters 46 and 61.

§57.981. Bag, Possession, and Length Limits.

(a) - (b) (No change.)

(c) There are no bag, possession, or length limits on game or non-game fish, except as provided in this subchapter.

(1) - (4) (No change)

(5) Except as provided in subsection (d) of this section, the statewide daily bag and length limits shall be as follows.

(A) - (F) (No change.)

(G) Drum, red.

(i) - (iii) (No change.)

(iv) Except as provided in this subparagraph for red drum taken under a digital product issued under the provisions of §53.18 of this title (relating to Digital Products), [~~During a license year,~~] one red drum exceeding the maximum length limit established by this subparagraph may be retained per license year when affixed with a properly executed Red Drum Tag, a properly executed Exempt Angler Red Drum Tag, or with a properly executed Duplicate Exempt Red Drum Tag, and one red drum over the stated maximum length limit may be retained when affixed with a properly executed Bonus Red Drum Tag. Any fish retained under authority of a Red Drum Tag, an Exempt Angler Red Drum Tag, a Duplicate Exempt Red Drum Tag, or a Bonus Red Drum Tag may be retained in addition to the daily bag and possession limit as provided in this section.

(v) A person who lawfully takes a red drum exceeding the maximum length limit under a digital product [~~license~~] issued under the provisions of §53.18 of this title [~~§53.3(a)(12) this title (relating to Super Combination Hunting and Fishing License Packages) or under a lifetime license with the digital tagging option provided by §53.4(a)(1) of this title (relating to Lifetime Licenses) that exceeds the maximum length limit established by this subparagraph~~] is exempt from any requirement of Parks and Wildlife Code or this subchapter regarding the use of physical [~~license~~] tags for that species; however, that person shall immediately upon take ensure that a harvest report is created and submitted via a mobile or web application provided by the department for that purpose. If the absence of data connectivity prevents the receipt of a confirmation number from the department following the report required by this subparagraph, the person who took the red drum is responsible for ensuring that the report required by this subparagraph is uploaded to the department immediately upon the availability of network connectivity.

(vi) It is an offense for any person to possess a red drum exceeding the maximum length established by this subparagraph under a digital product [~~license or digital tagging~~] option without being in immediate physical possession of an electronic device that is:

(I) - (II) (No change.)

(vii) (No change.)

(H) - (N) (No change.)

(O) Seatrout, spotted.

(i) - (iii) (No change.)

(iv) Except as provided in clause (v)(II) of this subparagraph, a person may retain [~~Only~~] one spotted seatrout greater than 28 [~~30~~] inches [~~may be retained~~] per license year [~~day~~]. A spotted seatrout retained under this clause [~~subclause~~] counts as part of the daily bag and possession limit.

(v) During a license year, a person fishing under an appropriate physical product may:

(I) retain one spotted seatrout exceeding the length limit established by clause (iv) this subparagraph, provided a properly executed Spotted Seatrout Tag, a properly executed Exempt Angler Spotted Seatrout Tag, or a properly executed Duplicate Exempt Spotted Seatrout Tag has been affixed to the fish; and

(II) additionally, may retain one spotted seatrout exceeding the length limit established by clause (iv) of this subparagraph in addition to a spotted seatrout retained under the provisions of subclause (I) of this clause, provided a properly executed Bonus Spotted Seatrout Tag or properly executed Duplicate Bonus Spotted Seatrout Tag has been affixed to the fish.

(vi) It is an offense for any person to possess a spotted seatrout exceeding the length limit established by clause (iv) of this subparagraph under a digital product issued under the provisions of §53.18 of this title (relating to Digital Products) without being in immediate physical possession of an electronic device that is:

(I) loaded with the mobile or web application designated by the department for harvest reporting under this section; and

(II) capable of uploading the harvest report required by this section.

(vii) A person who takes a spotted seatrout under a digital product issued under the provisions of §53.18 of this title or under a lifetime license with the digital tagging option provided by §53.4(a)(1) of this title (relating to Lifetime Licenses) that exceeds the length limit established by clause (iv) of this subparagraph is exempt from any requirement of Parks and Wildlife Code or this subchapter regarding the use of physical license products for spotted seatrout; however, that person shall immediately upon take ensure that a harvest report is created and submitted via a mobile or web application provided by the department for that purpose. If the absence of data connectivity prevents the receipt of a confirmation number from the department following the report required by this subparagraph, the person who took the spotted seatrout is responsible for ensuring that the report required by this subsection is uploaded to the department immediately upon the availability of network connectivity.

(viii) A person who is fishing under a license identified in §53.4(a)(1) of this title and selected the fulfilment of physical tags must comply with the tagging requirements of this chapter that are applicable to the tagging of spotted seatrout.

(P) - (Y) (No change.)

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 February 10, 2025.

TRD-202500463
James Murphy
General Counsel
Texas Parks and Wildlife Department
Earliest possible date of adoption: March 23, 2025
For further information, please call: (512) 389-4775

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31 TAC §57.984, §57.985

The repeals are proposed under the authority of Parks and Wildlife Code, §46.0085, which authorizes the department to issue tags for finfish species allowed by law to be taken during each year or season from coastal waters of the state to holders of licenses authorizing the taking of finfish species; §46.0086, which authorizes the commission to prescribe tagging requirements for the take of finfish; §50.004, which requires the department to issue and prescribe the form and manner of issuance for combination hunting and fishing licenses, including identification and compliance requirements; and Chapter 61, which requires the commission to regulate the periods of time when it is lawful to hunt, take, or possess game animals, game birds, or aquatic animal life in this state; the means, methods, and places in which it is lawful to hunt, take, or possess game animals, game birds, or aquatic animal life in this state; the species, quantity, age or size, and, to the extent possible, the sex of the game animals, game birds, or aquatic animal life authorized to be hunted, taken, or possessed; and the region, county, area, body of water, or portion of a county where game animals, game birds, or aquatic animal life may be hunted, taken, or possessed.

The proposed repeals affect Parks and Wildlife Code, Chapters 46 and 61.

§57.984. Special Provisions - Digital Exempt Angler Tags.

§57.985. Spotted Seatrout- Special Provisions.

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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James Murphy
General Counsel
Texas Parks and Wildlife Department
Earliest possible date of adoption: March 23, 2025
For further information, please call: (512) 389-4775

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DIVISION 3. STATEWIDE COMMERCIAL FISHING PROCLAMATION

31 TAC §57.992

The amendment is proposed under the authority of Parks and Wildlife Code, Chapter 61, which requires the commission to regulate the periods of time when it is lawful to hunt, take, or possess game animals, game birds, or aquatic animal life in this state; the means, methods, and places in which it is lawful to hunt, take, or possess game animals, game birds, or aquatic animal life in this state; the species, quantity, age or size, and, to the extent possible, the sex of the game animals, game birds, or aquatic animal life authorized to be hunted, taken, or possessed; and the region, county, area, body of water, or portion of a county where game animals, game birds, or aquatic animal life may be hunted, taken, or possessed.

The proposed amendment affects Parks and Wildlife Code, Chapter 61.

§57.992. Bag, Possession, and Length Limits.

(a) (No change.)

(b) There are no bag, possession, or length limits on game fish, non-game fish, or shellfish, except as otherwise provided in this subchapter.

(1) - (3) (No change.)

(A) Amberjack, greater.

(i) (No change.)

(ii) Minimum length: 40 [~~34~~] inches.

(iii) (No change.)

(B) - (N) (No change.)

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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James Murphy
General Counsel
Texas Parks and Wildlife Department
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CHAPTER 58. OYSTERS, SHRIMP, AND FINFISH

The Texas Parks and Wildlife Department proposes amendments to 31 TAC §58.21 and §58.164.

The proposed amendment to §58.21, concerning Taking or Attempting to Take Oysters from Public Oyster Beds; General Rules, would eliminate provisions that expired on their own terms on November 1, 2024, and are therefore no longer necessary.

The proposed amendment to §58.164, concerning Shrimping Inside Waters - Commercial Bait Shrimping, would make nonsubstantive changes to insert a missing preposition in subsection (b)(2)(A) and eliminate duplicated language in subsection (d). The Texas Parks and Wildlife Commission finds that the alterations are prudent because they eliminate possible confusion.

The proposed amendments are a result of the department's review of its regulations under the provisions of Government Code, §2001.039, which requires each state agency to review each of its regulations no less frequently than every four years and to re-adopt, adopt with changes, or repeal each rule as a result of the review.

Robert Macdonald, Regulations Coordinator, has determined that for each of the first five years that the rules as proposed are in effect, there will be no fiscal implications to state or local governments as a result of administering or enforcing the rules.

Mr. Macdonald also has determined that for each of the first five years the rules as proposed are in effect, the public benefit anticipated as a result of enforcing or administering the proposed rules will be accurate regulations.

There will be no adverse economic effect on persons required to comply with the rules as proposed.

Under the provisions of Government Code, Chapter 2006, a state agency must prepare an economic impact statement and a regulatory flexibility analysis for a rule that may have an adverse economic effect on small businesses, micro-businesses, or rural communities. As required by Government Code, §2006.002(g), the Office of the Attorney General has prepared guidelines to assist state agencies in determining a proposed rule's potential adverse economic impact on small and microbusinesses and rural communities. Those guidelines state that an agency need only consider a proposed rule's direct adverse economic impacts to determine if any further analysis is required. The department considers "direct economic impact "to mean a requirement that would directly impose recordkeeping or reporting requirements; impose taxes or fees; result in lost sales or profits; adversely affect market competition; or require the purchase or modification of equipment or services.

The department has determined that the proposed rules do not affect small businesses, micro-businesses, or rural communities. Therefore, neither the economic impact statement nor the regulatory flexibility analysis described in Government Code, Chapter 2006, is required.

The department has not drafted a local employment impact statement under the Administrative Procedures Act, §2001.022, as the agency has determined that the rules as proposed will not impact local economies.

The department has determined that Government Code, §2001.0225 (Regulatory Analysis of Major Environmental Rules), does not apply to the proposed rules.

The department has determined that there will not be a taking of private real property, as defined by Government Code, Chapter 2007, as a result of the proposed rules.

In compliance with the requirements of Government Code, §2001.0221, the department has prepared the following Government Growth Impact Statement (GGIS). The rules as proposed, if adopted, will: neither create nor eliminate a government program; not result in an increase or decrease in the number of full-time equivalent employee needs; not result in a need for additional General Revenue funding; not affect the amount of any fee; not create a new regulation; not limit, expand, or repeal an existing regulation; neither increase nor decrease the number of individuals subject to regulation; and not positively or adversely affect the state's economy.

Comments on the proposed rules may be submitted to Robert Macdonald (512) 389-4775, email: robert.macdonald@tpwd.texas.gov. Comments also may be submitted via the department's website at http://www.tpwd.texas.gov/business/feedback/public_comment/.

SUBCHAPTER A. STATEWIDE OYSTER FISHERY PROCLAMATION

31 TAC §58.21

The amendment is proposed under Parks and Wildlife Code, §76.301, which authorizes the commission to regulate the taking, possession, purchase and sale of oysters, including prescribing the times, places, conditions, and means and manner of taking oysters.

The proposed amendment affects Parks and Wildlife Code, Chapter 76.

§58.21. Taking or Attempting to Take Oysters from Public Oyster Beds: General Rules.

(a) - (b) (No change.)

(c) Area Closures.

(1) (No change.)

(2) No person may take or attempt to take oysters within an area described in this paragraph. The provisions of subparagraphs (A)(i)-(ii) cease effect on November 1, 2025. The provisions of subparagraph (A)(iii)-(iv) cease effect on November 1, 2026. [~~The provisions of subparagraph (B) of this paragraph cease on November 1, 2024.~~]

(A) Galveston Bay.

(i) - (iv) (No change.)

[~~(B) Espiritu Santo Bay- Josephine's Reef. The area within the boundaries of a line beginning at 28° 18' 42.6"N, 96° 35' 48.9"W (28.311833°N, -96.596916°W; corner marker buoy A); thence, to 28° 18' 34.7"N, 96° 35' 42.0"W (28.309651°N, -96.594988°W; corner marker buoy B); thence to 28° 18' 22.1"N, 96° 36' 00.3"W (28.306142°N, -96.600075°W; corner marker buoy C); thence to 28° 18' 30.0"N, 96° 36' 07.2"W (28.308324°N, -96.602004°W; corner marker buoy D); and thence back to corner marker buoy A.~~]

(B) [~~(C)~~] Christmas Bay, Brazoria County.

(C) [~~(D)~~] Carancahua Bay, Calhoun and Matagorda County.

(D) [~~(E)~~] Powderhorn Lake, Calhoun County.

(E) [~~(F)~~] Hynes Bay, Refugio County.

(F) [~~(G)~~] St. Charles Bay, Aransas County.

(G) [~~(H)~~] South Bay, Cameron County.

(H) [~~(I)~~] Mesquite Bay, Aransas and Calhoun counties.

(I) [~~(J)~~] Carlos Bay, Aransas County. The area within the boundaries of Carlos Bay from the border of Mesquite Bay to a line beginning at 28° 06' 52.19"N, 96° 55' 32.52"W (28.11450°N, -96.92570°W) and ending at 28° 06' 38.19"N, 96° 53' 17.41"W (28.11061°N, -96.88817°W).

(J) [~~(K)~~] Ayres Bay, Calhoun County. The area within the boundaries of Ayres Bay from the border of Mesquite Bay to a line beginning at 28° 12' 50.18"N, 96° 48' 44.53"W (28.21394°N, -96.81237°W) and ending at 28° 11' 17.05"N, 96° 47' 32.38"W (28.18807°N, -96.79233°W).

(K) [~~(L)~~] Areas along all shorelines extending 300 feet from the water's edge, including all oysters (whether submerged or not) landward of this 300-foot line.

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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James Murphy
General Counsel
Texas Parks and Wildlife Department
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SUBCHAPTER B. STATEWIDE SHRIMP FISHERY PROCLAMATION

31 TAC §58.164

The amendment is proposed under Parks and Wildlife Code, §77.007, which authorizes the commission to regulate the catching, possession, purchase, and sale of shrimp.

The proposed amendment affects Parks and Wildlife Code, Chapter 77.

§58.164. Shrimping Inside Waters' Commercial Bait Shrimping.

(a) (No change.)

(b) Commercial bait-shrimp season.

(1) (No change.)

(2) Legal shrimping hours.

(A) From August 15 through March 31 legal shrimping hours are 30 minutes before sunrise to 30 minutes after sunset.

(B) - (C) (No change.)

(c) (No change.)

(d) Size limits [~~Size limits~~]: Shrimp of any size may be retained when caught lawfully during commercial bait-shrimp operations in inside waters.

(e) (No change.)

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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James Murphy
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CHAPTER 65. WILDLIFE

The Texas Parks and Wildlife Department proposes amendments to 31 TAC §§65.7, 65.8, 65.10, 65.29, 65.42, 65.62, and 65.64, concerning the Statewide Hunting Proclamation.

The proposed amendments to §65.7, concerning Application, §65.8, concerning Alternative Licensing System, and §65.10, concerning Possession of Wildlife Resources, would make conforming changes to accommodate proposed amendments to Chapter 53, concerning Finance, published elsewhere in this issue of the *Texas Register*, that would provide for the issuance of digital versions of all recreational hunting licenses, stamp endorsements, tags, and selected permits that are currently available directly to the public as physical products. In 2021, the department launched a pilot program to determine the feasibility of implementing digital versions of physical licenses, stamp endorsements, tags, and permits. The results of the pilot program were favorable, and the department is therefore proceeding with respect to making all recreational license products currently available directly to the public available in a digital version.

The proposed amendment to §65.29, concerning Managed Lands Deer Program (MLDP), would allow the take of mule deer under the appropriate MLDP tag by any lawful means at any time during the period of validity of the tag (from the Saturday closest to September 30 through the last Sunday in January). Under current rule, lawful means of harvest is restricted to lawful archery equipment from the Saturday closest to September 30 for 35 consecutive days, which mirrors the current archery-only season dates established in the county regulations in §65.42, concerning Deer. Because the total harvest on MLDP properties is controlled by the department through the issuance of tags issued to landowners, the department has determined there is no biological reason not to provide landowners and land managers enrolled in the MLDP the latitude to attain their harvest quota at their own discretion by any means lawful in the county of take (which has long been the case on MLDP properties with respect to the harvest of white-tailed deer).

The proposed amendment to §65.42, concerning Deer, would expand the archery-only season for mule deer from 35 days to 62 days in Brewster, Crane, Crockett, Culberson, Ector, El Paso, Hudspeth, Jeff Davis, Loving, Midland, Pecos, Presidio, Reagan, Reeves, Terrell, Upton, Val Verde, Ward, and Winkler counties. In addition, the proposed amendment would expand the archery-only season for mule deer from 35 to 56 days in those Panhandle counties that have an archery-only season for mule deer. The proposed amendment is intended to provide additional hunting opportunity for archery enthusiasts and will not result in depletion or waste of the resource, as hunter success with respect to archery harvest of mule deer is generally quite low and the harvest regulations for antlerless mule deer are very conservative. The proposed amendment would in essence continue the current archery season in each affected county until opening day of the general season. The proposed amendment would also make conforming changes to provisions governing digital products, for reasons discussed earlier in this preamble. Finally, the proposed amendment to §65.42 would eliminate subsection (c)(6) which is no longer necessary because the department has eliminated CWD management zones.

The proposed amendment to §65.62, concerning Quail: Open Seasons, Bag and Possession Limits, would alter the current season structure by closing the season on the last day of February rather than the last Sunday in February. Under the existing regulatory structure, the last Sunday in February often falls on a different date each year, potentially creating confusion amongst hunters, landowners, and other interested parties. The proposed change would result in an additional 2.6 days of hunting per year over the next decade, with similar levels thereafter, which the department has determined will not result in depletion or waste of the resource.

The proposed amendment to §65.64, concerning Turkey, would open a fall (first Saturday in November through the first Sunday in January, either sex) and spring (Saturday closest to April 1 for 44 consecutive days, gobblers or bearded hens) season for turkeys in Lubbock County, with a four-bird annual bag limit. The department has determined that there is no biological reason not to allow the take of turkey in Lubbock County and that the proposed open seasons will not result in depletion or waste. The proposed amendment also would make conforming changes to provisions governing digital products, for reason discussed earlier in this preamble, clarify the boundaries for turkey seasons in

Hill County to accommodate the fact that Interstate Highway 35 is divided into I-35 West and I-35 East, and insert season dates that were inadvertently omitted in a previous publication.

Robert Macdonald, Regulations Coordinator, has determined that for each of the first five years that the rules as proposed are in effect, there will be no fiscal implications to state or local governments as a result of administering or enforcing the rules.

Mr. Macdonald also has determined that for each of the first five years that the rules as proposed are in effect, the public benefit anticipated as a result of enforcing or administering the proposed rules will be the dispensation of the agency's statutory duty to protect and conserve the resources of this state, the duty to equitably distribute opportunity for the enjoyment of those resources among the citizens, and the execution of the commission's policy to maximize recreational opportunity within the precepts of sound biological management practices.

There will be no adverse economic effect on persons required to comply with the rules as proposed.

Under the provisions of Government Code, Chapter 2006, a state agency must prepare an economic impact statement and a regulatory flexibility analysis for a rule that may have an adverse economic effect on small businesses, micro-businesses, or rural communities. As required by Government Code, §2006.002(g), the Office of the Attorney General has prepared guidelines to assist state agencies in determining a proposed rule's potential adverse economic impact on small and microbusinesses and rural communities. Those guidelines state that an agency need only consider a proposed rule's direct adverse economic impacts to determine if any further analysis is required. The department considers "direct economic impact "to mean a requirement that would directly impose recordkeeping or reporting requirements; impose taxes or fees; result in lost sales or profits; adversely affect market competition; or require the purchase or modification of equipment or services.

The department has determined that the proposed rules regulate various aspects of recreational license privileges that allow individual persons to pursue and harvest wildlife resources in this state and therefore do not directly affect small businesses, micro-businesses, or rural communities. Therefore, neither the economic impact statement nor the regulatory flexibility analysis described in Government Code, Chapter 2006, is required.

The department has not drafted a local employment impact statement under the Administrative Procedures Act, §2001.022, as the agency has determined that the rules as proposed will not impact local economies.

The department has determined that Government Code, §2001.0225 (Regulatory Analysis of Major Environmental Rules), does not apply to the proposed rules.

The department has determined that there will not be a taking of private real property, as defined by Government Code, Chapter 2007, as a result of the proposed rules.

In compliance with the requirements of Government Code, §2001.0221, the department has prepared the following Government Growth Impact Statement (GGIS). The ruled as proposed, if adopted, will: neither create nor eliminate a government program; not result in an increase or decrease in the number of full-time equivalent employee needs; not result in a need for additional General Revenue funding; not affect the amount of any fee; not create a new regulation; not limit an existing regulation, but will expand an existing regulation (by lengthening archery seasons for mule deer); neither increase nor decrease the number of individuals subject to regulation; and not positively or adversely affect the state's economy.

Comments concerning the proposed rules affecting big game species may be submitted to Shawn Gray at (432) 837-0666, e-mail: shawn.gray@tpwd.texas.gov. Comments concerning the proposed rules affecting turkey may be submitted to Shaun Oldenburger at (512) 757-6067, email: shaun.oldenburger@tpwd.texas.gov. Comments also may be submitted via the department's website at https://tpwd.texas.gov/business/feedback/public_comment/.

SUBCHAPTER A. STATEWIDE HUNTING PROCLAMATION

DIVISION 1. GENERAL PROVISIONS

31 TAC §§65.7, 65.8, 65.10, 65.29

The amendments are proposed under the authority of Parks and Wildlife Code, Chapter 61, which requires the commission to regulate the periods of time when it is lawful to hunt, take, or possess game animals, game birds, or aquatic animal life in this state; the means, methods, and places in which it is lawful to hunt, take, or possess game animals, game birds, or aquatic animal life in this state; the species, quantity, age or size, and, to the extent possible, the sex of the game animals, game birds, or aquatic animal life authorized to be hunted, taken, or possessed; and the region, county, area, body of water, or portion of a county where game animals, game birds, or aquatic animal life may be hunted, taken, or possessed.

The proposed amendments affect Parks and Wildlife Code, Chapter 61.

§65.7. Harvest Log.

(a) The provisions of this subsection apply only to a person who has acquired [~~in possession of~~] a physical license purchased through an automated point-of-sale system and do not apply to a person who has acquired a digital license identified in §53.18 of this title (relating to Digital Products) [~~issued by the department pursuant to §53.3(a)(12) of this title (relating to Combination Hunting and Fishing License Packages), §53.4 of this title (relating to Lifetime Licenses) or §53.5(a)(3) of this title (relating to Recreational Hunting License, Stamps, and Tags)~~].

(1) - (2) (No change.)

(b) (No change.)

§65.8. Alternative Licensing System.

(a) - (c) (No change.)

(d) This section does not apply to the digital products [~~licenses~~] identified in §53.18 of this title (relating to Digital Products) [~~§53.3(a)(12) of this title (relating to Combination Hunting and Fishing License Packages), §53.4 of this title (relating to Lifetime Licenses), or §53.5(a)(3) (relating to Recreational Hunting Licenses, Stamps, and Tags)~~].

§65.10. Possession of Wildlife Resources.

(a) (No change.)

(b) Under authority of Parks and Wildlife Code, §42.0177, the tagging requirements of Parks and Wildlife Code, §42.018, are modified as follows.

(1) - (4) (No change.)

(5) Except as provided in paragraph (3) of this subsection, the tagging requirements for deer and turkey taken under a digital license issued under the provisions of §53.18 of this title (relating to Digital Products) [~~§53.3(a)(12) of this title (relating to Super Combination Hunting and Fishing License Packages), under the digital tagging option of §53.4 of this title (relating to Lifetime Licenses), and §53.5(a)(3) of this title (relating to Recreational Hunting License, Stamps, and Tags)~~] are prescribed in subsection (e) of this section.

(6) (No change.)

(c) - (d) (No change.)

(e) A person who lawfully kills a deer or turkey under the [~~a~~] digital version of a license identified in §53.18 of this title [~~issued under the provisions of §53.3(a)(12) of this title, the digital tagging option under §53.4 of this title or §53.5(a)(3) of this title (relating to Recreational Hunting License, Stamps, and Tags)~~] is exempt from any requirement of Parks and Wildlife Code or this subchapter regarding the use or possession of physical license tags for those species; however, that person shall ensure that immediately upon take a harvest report is created and submitted via a mobile or web application provided by the department for that purpose.

(1) - (3) (No change.)

(f) - (m) (No change.)

§65.29. Managed Lands Deer Program (MLDP).

(a) - (c) (No change.)

(d) MLDP--Mule Deer.

(1) The provisions of subsection (c)(2)(A) - (H) of this section also shall govern the authorization and conduct of program participation with respect to mule deer, except[~~:~~]

[~~(1)~~] the harvest of mule deer shall occur only between the Saturday closest to September 30 and the last Sunday of January, during which mule deer may be taken by any lawful means[~~, as follows:~~]

[~~(A) from the Saturday closest to September 30 for 35 consecutive days, the lawful means of harvest is restricted to lawful archery equipment; and~~]

[~~(B) from the first Saturday in November through the last Sunday in January any lawful means may be used to harvest deer; and~~]

(2) Program [~~program~~] eligibility is specifically restricted to tracts of land in counties for which an open season for mule deer is provided under §65.42 of this title.

(e) - (f) (No change.)

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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James Murphy
General Counsel
Texas Parks and Wildlife Department
Earliest possible date of adoption: March 23, 2025
For further information, please call: (512) 389-4775

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DIVISION 2. OPEN SEASONS AND BAG LIMITS

31 TAC §§65.42, 65.62, 65.64

The amendments are proposed under the authority of Parks and Wildlife Code, Chapter 61, which requires the commission to regulate the periods of time when it is lawful to hunt, take, or possess game animals, game birds, or aquatic animal life in this state; the means, methods, and places in which it is lawful to hunt, take, or possess game animals, game birds, or aquatic animal life in this state; the species, quantity, age or size, and, to the extent possible, the sex of the game animals, game birds, or aquatic animal life authorized to be hunted, taken, or possessed; and the region, county, area, body of water, or portion of a county where game animals, game birds, or aquatic animal life may be hunted, taken, or possessed.

The proposed amendments affect Parks and Wildlife Code, Chapter 61.

§65.42. Deer.

(a) General.

(1) - (4) (No change.)

(5) In the counties or portions of counties listed in subsection (b)(2)(G) of this section, antlerless deer harvested on properties not subject to the provisions of §65.29 of this title (relating to Managed Lands Deer (MLD) Programs) must be reported via the department's internet or mobile application within 24 hours of the time of kill, including antlerless deer harvested during the special seasons established by subsection (b)(4) and (5) of this section. This paragraph does not apply to antlerless deer harvested under a digital license issued by the department pursuant to §53.18 of this title (relating to Digital Products) [~~§53.3(a)(12) of this title (relating to Super Combination Hunting and Fishing Packages), a valid license with digital tags issued under §53.4 of this title (relating to Lifetime Licenses), or a valid digital license issued under §53.5(a)(3) of this title (relating to Recreational Hunting License, Stamps, and Tags)~~], which must be reported as required under §65.10 of this title (relating to Possession of Wildlife Resources).

(b) (No charge.)

(c) Mule deer. The open seasons and bag limits for mule deer shall be as follows:

(1) - (4) (No change.)

(5) Archery-only open seasons and bag and possession limits shall be as follows.

(A) In Andrews, Armstrong, Bailey, Borden, Briscoe, Carson, Castro, Childress, Cochran, Coke, Collingsworth, Cottle, [~~Crane, Crockett,~~] Crosby, [~~Culberson,~~] Dallam, Dawson, Deaf Smith, Dickens, Donley, [~~Ector, El Paso,~~] Fisher, Floyd, Foard, Gaines, Garza, Gray, Hale, Hall, Hansford, Hardeman, Hartley, Hemphill, Hockley, [~~Hudspeth,~~] Hutchinson, [~~Jeff Davis,~~] Kent, King, Knox, Lamb, Lipscomb, [~~Loving,~~] Lubbock, Lynn, Martin, [~~Midland,~~] Moore, Motley, Ochiltree, Oldham, Parmer, Potter, [~~Presidio,~~] Randall, [~~Reagan, Reeves,~~] Roberts, Scurry, Sherman, Stonewall, Swisher, Terry, [~~Upton, Val Verde, Ward,~~] Wheeler, [~~Winkler,~~] and Yoakum counties:

(i) from the Saturday closest to September 30 for 56 [~~35~~] consecutive days; and

(ii) (No change.)

(B) In Crane, Crockett, Culberson, Ector, El Paso, Hudspeth, Jeff Davis, Loving, Midland, Presidio, Reagan, Reeves, Upton, Val Verde, Ward, and Winkler counties:

(i) from the Saturday closest to September 30 for 62 consecutive days; and

(ii) bag limit: one buck.

(C) [~~(B)~~] In Brewster, Pecos, and Terrell counties:

(i) from the Saturday closest to September 30 for 62 [~~35~~] consecutive days.

(ii) (No change.)

(D) [~~(C)~~] In all other counties, there is no archery-only open season for mule deer.

[~~(6) There are no antler restrictions within a Containment Zone or Surveillance Zone established under the provisions of Subchapter B, Division 1 of this chapter.~~]

§65.62. Quail: Open Seasons, Bag and Possession Limits.

(a) In all counties there is an open season for quail beginning the Saturday closest to October 28 through the last day [~~Sunday~~] in February.

(b) - (d) (No change.)

§65.64. Turkey.

(a) (No change.)

(b) The open seasons and bag limits for turkey shall be as follows.

(1) Fall seasons and bag limits:

(A) - (B) (No change.)

(C) The counties and portions of counties listed in this subparagraph are in the Fall North Zone. In Archer, Armstrong, Bandera, Baylor, Bell (west of Interstate Highway 35), Bexar, Blanco, Borden, Bosque, Briscoe, Brown, Burnet, Callahan, Carson, Childress, Clay, Coke, Coleman, Collingsworth, Comal (west of Interstate Highway 35), Comanche, Concho, Cooke, Coryell, Cottle, Crane, Crockett, Crosby, Dawson, Denton, Dickens, Donley, Eastland, Ector, Edwards, Erath, Fisher, Floyd, Foard, Garza, Gillespie, Glasscock, Gray, Hall, Hamilton, Hardeman, Hartley, Haskell, Hays (west of Interstate Highway 35), Hemphill, Hill (west of Interstate Highway 35 East [~~35~~]), Hood, Howard, Hutchinson, Irion, Jack, Johnson, Jones, Kendall, Kent, Kerr, Kimble, King, Kinney (north of U.S. Highway 90), Knox, Lampasas, Lipscomb, Llano, Lubbock, Lynn, Martin, Mason, McCulloch, McLennan (west of Interstate Highway 35), Medina (north of U.S. Highway 90), Menard, Midland, Mills, Mitchell, Montague, Moore, Motley, Nolan, Ochiltree, Oldham, Palo Pinto, Parker, Potter, Randall, Reagan, Real, Roberts, Runnels, San Saba, Schleicher, Scurry, Shackelford, Somervell, Stephens, Sterling, Stonewall, Sutton, Swisher, Tarrant, Taylor, Throckmorton, Tom Green, Travis (west of Interstate Highway 35), Upton, Uvalde (north of U.S. Highway 90), Val Verde (north of a line beginning at the International Bridge and proceeding along Spur 239 to U.S. Hwy. 90 and thence to the Kinney County line), Ward, Wheeler, Wichita, Wilbarger, Williamson (west of Interstate Highway 35), Wise, and Young counties, there is a fall general open season.

(i) - (ii) (No change.)

(2) (No change.)

(3) Spring season and bag limits.

(A) The counties and portions of counties listed in this subparagraph are in the Spring North Zone. In Archer, Armstrong, Bandera, Baylor, Bell (west of Interstate Highway 35), Bexar, Blanco, Borden, Bosque, Briscoe, Brown, Burnet, Callahan, Carson, Childress, Clay, Coke, Coleman, Collingsworth, Comal (west of Interstate Highway 35), Comanche, Concho, Cooke, Coryell, Cottle, Crane, Crockett, Crosby, Dawson, Denton, Dickens, Donley, Eastland, Ector, Edwards, Ellis (west of Interstate Hwy. 35), Erath, Fisher, Floyd, Foard, Garza, Gillespie, Glasscock, Gray, Guadalupe (south of Interstate Highway 10), Hall, Hamilton, Hardeman, Hartley, Haskell, Hays (west of Interstate Highway 35), Hemphill, Hill (west of Interstate Highway 35 East [~~35~~]), Hood, Howard, Hutchinson, Irion, Jack, Johnson, Jones, Kendall, Kent, Kerr, Kimble, King, Kinney (north of U.S. Hwy. 90), Knox, Lampasas, Lipscomb, Llano, Lubbock, Lynn, Martin, Mason, McCulloch, McLennan (west of Interstate Highway 35), Medina (north of U.S. Hwy. 90), Menard, Midland, Mills, Mitchell, Montague, Moore, Motley, Nolan, Ochiltree, Oldham, Palo Pinto, Parker, Potter, Randall, Reagan, Real, Roberts, Runnels, San Saba, Schleicher, Scurry, Shackelford, Somervell, Stephens, Sterling, Stonewall, Sutton, Swisher, Tarrant, Taylor, Throckmorton, Tom Green, Travis (west of Interstate Highway 35), Upton, Uvalde (north of U.S. Hwy. 90), Val Verde (north of a line beginning at the International Bridge and proceeding along Spur 239 to U.S. Hwy. 90 and thence to the Kinney County line), Ward, Wheeler, Wichita, Wilbarger, Williamson (west of Interstate Highway 35), Wise, and Young counties, there is a spring general open season.

(i) - (ii) (No change.)

(B) (No change.)

(C) In Bastrop, Brewster, Caldwell, Colorado, Comal (east of Interstate Highway 35), Fayette, Guadalupe (north of I-10), Hays (east of Interstate Highway 35), Hill (east of Interstate Highway 35 East [~~35~~]), Jackson, Jeff Davis, Lavaca, Lee, Matagorda, McLennan (east of Interstate Highway 35), Pecos, Terrell, Travis (east of Interstate Highway 35), and Wharton counties, there is a spring general open season.

(i) Open season: from April 1 through April 30.

(ii) (No change.)

(D) (No change.)

(4) (No change.)

(c) Except as provided by §65.10 of this title for turkeys harvested under a digital license issued pursuant to §53.18 of this title (relating to Digital Products) [~~§53.3(a)(12) of this title, a valid license with digital tags under §53.4 of this title, or a valid digital license under §53.5(a)(3) of this title~~], all harvested turkeys must be registered via the department's internet or mobile application within 24 hours of the time of kill.

(d) (No change.)

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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James Murphy
General Counsel
Texas Parks and Wildlife Department
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SUBCHAPTER N. MIGRATORY GAME BIRD PROCLAMATION

31 TAC §§65.314 - 65.320

The Texas Parks and Wildlife Department (the department) proposes amendments to 31 TAC §§65.314 - 65.320, concerning the Migratory Game Bird Proclamation.

The United States Fish and Wildlife Service (Service) issues annual frameworks for the hunting of migratory game birds in the United States. Regulations adopted by individual states may be more restrictive than the federal frameworks but may not be less restrictive. Responsibility for establishing seasons, bag limits, means, methods, and devices for harvesting migratory game birds within Service frameworks is delegated to the Texas Parks and Wildlife Commission (Commission) under Parks and Wildlife Code, Chapter 64, Subchapter C.

With exceptions as noted, the proposed amendments specify the season dates for hunting the various species of migratory game birds for 2025-2026 seasons. Except as noted in the discussion of the proposed seasons for the Special White-winged Dove Area (SWWDA), teal, falconry, ducks in the High Plains Mallard Management Unit (HPMMU), the season dates for rails and gallinules, and the proposed daily bag limits for pintail, the rules as proposed retain the season structure and bag limits for all species of migratory game birds from last year while adjusting the season dates to allow for calendar shift (i.e., to ensure that seasons open on the desired day of the week), since dates from a previous year do not fall on the same days in following years.

The proposed amendment to §65.314, concerning Doves (Mourning, White-Winged, White-Tipped, White-Fronted Doves), would again implement a slightly different structure for the SWWDA season than in years past. Under the federal frameworks, Texas is allowed 90 total days of dove hunting opportunity in the South Zone (which is also designated as a special management area for white-winged doves). Under the frameworks, the earliest possible date for full-day dove hunting in the South Dove Zone is September 14; however, Texas is also authorized to have up to six half-days of hunting opportunity between September 1 and September 19. Department survey data have consistently indicated strong hunter and landowner preference for the earliest possible hunting opportunity available under the federal frameworks, as well as for maximal weekend hunting opportunity during the SWWDA season, since nearly half of the hunters in the SWWDA zone travel from outside of the zone. In a typical year, this would take the form of two three-day weekends of half-day special white-winged opportunity beginning on the earliest day possible under the frameworks. The 2025-26 calendar, however, presents a challenge because September 1, 2025, (the earliest possible day for SWWDA hunting) falls on a Monday, so there are not two complete three-day weekends available before the full-day dove hunting can begin. The department has determined that in keeping with hunter and landowner preference, this year's SWWDA dates would be best employed by implementing a five-day season structure of September 5-7 (a traditional three-day weekend) and September 12-13 (Friday and Saturday), which is the last two days before the earliest possible date that full-day dove hunting can be provided under the federal frameworks (September 14).

The proposed amendment to §65. 315, concerning Ducks, Coots, Mergansers, and Teal, would reduce the length of the early teal season from 16 days to nine days, which is the maximum allowed under this year's federal frameworks. The proposed amendment to §65.315 also would increase the HPMMU season by seven days. Under the federal frameworks, Texas is allowed 107 total days of duck hunting opportunity. Because the federal frameworks for 2025-26 mandate a seven-day reduction in early teal season opportunity, those seven days can be allocated elsewhere; therefore, the department proposes to add the seven days to the beginning of the season in the HPMMU to provide additional opportunity for species that arrive early in Texas, especially teal.

The proposed amendment to §65.315, concerning Ducks, Coots, Mergansers, and Teal, would also alter subsection (c) to increase the daily bag limit for pintails from one to three. The Service recently adopted a new Pintail Harvest Strategy that includes the option for a three-bird daily bag limit. In keeping with long-standing commission policy to provide the most liberal hunting opportunity possible under the federal frameworks, consistent with the tenets of sound biological management, the department therefore proposes to increase the bag limit in accordance with the Service's harvest strategy.

The proposed amendment to §65.319, concerning Gallinules, Rails, Snipe, Woodcock, would result in a slightly different season structure for rails and gallinules. Typically, the department establishes a split-season structure for rail and gallinule seasons, the first segment to run concurrently with the early teal season and the second segment to open concurrently with the South Zone duck season and run for 70 days (thereby utilizing the maximum number of days allotted for rail and gallinule seasons under the federal frameworks). Because of the seven-day reduction in the early teal season mandated under the federal frameworks, retaining the traditional season structure results in a nine-day first segment for rail and gallinule seasons, with seven days added to the end of the second segment, which the department believes optimizes hunting opportunity for rail and gallinule hunters.

The proposed amendment to §65.320, concerning Extended Falconry Seasons, would allow for expanded falconry opportunity for ducks, which is possible because of the additional seven days of opportunity resulting from the shortened early teal season discussed previously in this preamble.

Shaun Oldenburger, Wildlife Division Small Game Program Director, has determined that for the first five years that the amendments as proposed are in effect, there will be no additional fiscal implications to state or local governments of enforcing or administering the rules as proposed.

Mr. Oldenburger also has determined that for each of the first five years the proposed rules are in effect, the public benefit anticipated as a result of enforcing the rules as proposed will be the department's discharge of its statutory obligation to manage and conserve the state's populations of migratory game birds for the use and enjoyment of the public, consistent with the principles of sound biological management.

Under the provisions of Government Code, Chapter 2006, a state agency must prepare an economic impact statement and a

regulatory flexibility analysis for a rule that may have an adverse economic effect on small businesses, micro-businesses, or rural communities. As required by Government Code, §2006.002(g), the Office of the Attorney General has prepared guidelines to assist state agencies in determining a proposed rule's potential adverse economic impact on small and microbusinesses and rural communities. Those guidelines state that an agency need only consider a proposed rule's "direct adverse economic impacts" to determine if any further analysis is required. The department considers "direct economic impact" to mean a requirement that would directly impose recordkeeping or reporting requirements; impose taxes or fees; result in lost sales or profits; adversely affect market competition; or require the purchase or modification of equipment or services.

The department has determined that the proposed rules regulate various aspects of recreational license privileges that allow individual persons to pursue and harvest migratory game bird resources in this state and therefore do not directly affect small businesses, micro-businesses, or rural communities. Therefore, neither the economic impact statement nor the regulatory flexibility analysis described in Government Code, Chapter 2006, is required.

There also will be no adverse economic effect on persons required to comply with the rules as proposed.

The department has not drafted a local employment impact statement under the Administrative Procedures Act, §2001.022, as the agency has determined that the rules as proposed will not impact local economies.

The department has determined that Government Code, §2001.0225 (Regulatory Analysis of Major Environmental Rules), does not apply to the proposed rules.

The department has determined that there will not be a taking of private real property, as defined by Government Code, Chapter 2007, as a result of the proposed rules.

In compliance with the requirements of Government Code, §2001.0221, the department has prepared the following Government Growth Impact Statement (GGIS). The rules as proposed, if adopted, will: neither create nor eliminate a government program; not result in an increase or decrease in the number of full-time equivalent employee needs; not result in a need for additional General Revenue funding; not affect the amount of any fee; not create, limit, or expand an existing regulation; neither increase nor decrease the number of individuals subject to regulation; and not positively or adversely affect the state's economy.

Comments on the proposed rules may be submitted to Shaun Oldenburger (Small Game Program Director) at (512) 389-4778, email: shaun.oldenburger@tpwd.texas.gov or via the department website at www.tpwd.texas.gov.

The amendments are proposed under Parks and Wildlife Code, Chapter 64, which authorizes the Commission and the Executive Director to provide the open season and means, methods, and devices for the hunting and possessing of migratory game birds.

The proposed amendments affect Parks and Wildlife Code, Chapter 64.

§65.314. Doves (Mourning, White-Winged, White-Tipped, White-Fronted Doves).

(a) (No change.)

(b) Seasons; Daily Bag Limits.

(1) North Zone.

(A) Dates: September 1- November 9, 2025 and December 19, 2025 - January 7, 2026 [~~September 1 - November 10, 2024 and December 20, 2024 - January 7, 2025~~].

(B) (No change.)

(2) Central Zone.

(A) Dates: September 1 - October 26, 2025 and December 12, 2025 - January 14, 2026 [~~September 1 - October 27, 2024 and December 13, 2024 - January 14, 2025~~].

(B) (No change.)

(3) South Zone and Special White-winged Dove Area.

(A) Special White-winged Dove Area Season.

(i) Dates: September 5-7, 12-13, 2025 [~~September 1-2, 6-8, 13, 2024~~].

(ii) (No change.)

(B) South Zone Season.

(i) Dates: September 14 - October 26, 2025 and December 12, 2025 - January 22, 2026 [~~September 14 - October 27, 2024 and December 13, 2024 - January 21, 2025~~].

(ii) (No change.)

§65.315. Ducks, Coots, Mergansers, and Teal.

(a) (No change.)

(b) Season dates and bag limits.

(1) HPMMU.

(A) For all species other than "dusky ducks": October 18-19 and October 24, 2025 - January 25, 2026 [~~October 26-27, 2024 and November 1, 2024 - January 26, 2025~~]; and

(B) "dusky ducks": October 27, 2025 - January 25, 2026 [~~November 4, 2024 - January 26, 2025~~].

(2) North Zone.

(A) For all species other than "dusky ducks": November 8-30, 2025 and December 6, 2025 - January 25, 2026 [~~November 9 - December 1, 2024 and December 7, 2024 - January 26, 2025~~]; and

(B) "dusky ducks": November 13-30, 2025 and December 6, 2025 - January 25, 2026 [~~November 14, 2024 - December 1, 2024 and December 7, 2024 - January 26, 2025~~].

(3) South Zone.

(A) For all species other than "dusky ducks": November 1-30, 2025 and December 13, 2025 - January 25, 2026 [~~November 2 - December 1, 2024 and December 14, 2024 - January 26, 2025~~]; and

(B) "dusky ducks": November 6-30, 2025 and December 13, 2025 - January 25, 2026 [~~November 7 - December 1, 2024 and December 14, 2024 - January 26, 2025~~].

(4) September teal-only season.

(A) (No change.)

(B) Dates: September 20-28, 2025 [~~14-29, 2024~~].

(c) Bag limits.

(1) The daily bag limit for ducks and mergansers is six in the aggregate, which may include no more than five mallards (only two of which may be hens); three wood ducks; one scaup (lesser scaup or greater scaup); two redheads; two canvasbacks; three pintails [~~one pintail~~]; and one "dusky" duck (mottled duck, Mexican duck, black duck and their hybrids) during the seasons established for those species in this section. For all species not listed, the daily bag limit shall be six. The daily bag limit for coots is 15.

(2) (No change.)

§65.316. Geese.

(a) (No change.)

(b) Season dates and bag limits.

(1) Western Zone.

(A) Light geese: November 1, 2025 - February 1, 2026 [~~November 2, 2024 - February 2, 2025~~]. The daily bag limit for light geese is five.

(B) Dark geese: November 1, 2025 - February 1, 2026 [~~November 2, 2024 - February 2, 2025~~]. The daily bag limit for dark geese is five.

(2) Eastern Zone.

(A) Light geese: November 1, 2025 - February 15, 2026 [~~November 2, 2024 - February 14, 2025~~]. The daily bag limit for light geese is five.

(B) Dark geese:

(i) Season: November 1, 2025 - January 25, 2026 [~~November 2, 2024 - January 26, 2025~~];

(ii) (No change.)

(c) September Canada goose season. Canada geese may be hunted in the Eastern Zone during the season established by this subsection. The season is closed for all other species of geese during the season established by this subsection.

(1) Season dates: September 13-28, 2025 [~~September 14-29, 2024~~].

(2) (No change.)

§65.317. Special Youth, Active-Duty Military, and Military Veteran Seasons.

(a) Special Youth Waterfowl Season. There shall be a Special Youth Season for waterfowl, during which the hunting, taking, and possession of geese, ducks, mergansers, and coots is restricted to licensed hunters 16 years of age and younger accompanied by a person 18 years of age or older, except for persons hunting by means of falconry under the provisions of §65.320 of this title (relating to Extended Falconry Seasons).

(1) HPMMU:

(A) season dates: October 11-12, 2025 [~~October 19-20, 2024~~];

(B) (No change.)

(2) North Duck Zone:

(A) season dates: November 1-2, 2025 [~~November 2-3, 2024~~];

(B) (No change.)

(3) South Duck Zone:

(A) season dates: October 25-26, 2025 [~~October 26-27, 2024~~];

(B) (No change.)

(b) Special Active-Duty Military and Military Veteran Migratory Game Bird Season.

(1) - (2) (No change.)

(3) Season Dates and Bag Limits.

(A) HPMMU:

(i) season dates: October 11-12, 2025 [~~October 19-20, 2024~~];

(ii) (No change.)

(B) North Duck Zone:

(i) season dates: November 1-2, 2025 [~~November 2-3, 2024~~];

(ii) (No change.)

(C) South Duck Zone:

(i) season dates: October 25-26, 2025 [~~October 26-27, 2024~~];

(ii) (No change.)

(4) (No change.)

§65.318. Sandhill Crane.

(a) (No change.)

(b) Season dates and bag limits.

(1) Zone A: October 25, 2025 - January 25, 2026 [~~October 26, 2024 - January 26, 2025~~]. The daily bag limit is three.

(2) Zone B: November 21, 2025 - January 25, 2026 [~~November 22, 2024 - January 26, 2025~~]. The daily bag limit is three.

(3) Zone C: December 13, 2025 - January 18, 2026 [~~December 14, 2024 - January 19, 2025~~]. The daily bag limit is two.

(c) (No change.)

§65.319. Gallinules, Rails, Snipe, Woodcock.

(a) Gallinules (moorhen or common gallinule and purple gallinule) may be taken in any county of this state during the season established in this subsection.

(1) Season dates: September 20-28 and November 1 - December 31, 2025 [~~September 14-29 and November 2 - December 25, 2024~~].

(2) (No change.)

(b) Rails may be taken in any county of this state during the season established by this subsection.

(1) Season dates: September 20-28 and November 1 - December 31, 2025 [~~September 14-29 and November 2 - December 25, 2024~~].

(2) (No change.)

(c) Snipe may be taken in any county of this state during the season established by this subsection.

(1) Season dates: November 1, 2025 - February 15, 2026 [~~November 2, 2024 - February 16, 2025~~].

(2) (No change.)

(d) Woodcock may be taken in any county of this state during the season established by this subsection.

(1) Season dates: December 18, 2025 - January 31, 2026 [~~December 18, 2024 - January 31, 2025~~].

(2) (No change.)

§65.320. Extended Falconry Seasons.

It is lawful to take the species of migratory birds listed in this section by means of falconry during the seasons established by this section.

(1) Mourning doves, white-winged doves and white-tipped doves: November 14 - November 30, 2025 [~~November 15 - December 1, 2024~~].

(2) Duck, gallinule, moorhen, rail, and woodcock: January 26 - February 15, 2026 [~~January 27 - February 10, 2025~~].

(3) - (4) (No change.)

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 February 10, 2025.

TRD-202500467
James Murphy
General Counsel
Texas Parks and Wildlife Department
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For further information, please call: (512) 389-4775

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TITLE 34. PUBLIC FINANCE

PART 1. COMPTROLLER OF PUBLIC ACCOUNTS

CHAPTER 5. FUNDS MANAGEMENT (FISCAL AFFAIRS)

SUBCHAPTER E. CLAIMS PROCESSING--PURCHASE VOUCHERS

34 TAC §5.54

The Comptroller of Public Accounts proposes amendments to §5.54 concerning consulting services contracts.

The legislation enacted within the last four years that provides the statutory authority for the amendments is Senate Bill 799, 87th Legislature, R.S., 2021.

The amendments to subsection (a) add a definition of "university system" because a reference to "university system" is being added in subsection (f)(1)(B) and delete the definition of "SPD" because references to "SPD" are being deleted from subsection (e).

The amendments to subsection (c)(1) delete the reference to subsection (d) because subsection (d) is being deleted from this section; add a reference to Government Code, §2254.028(a)(3) because Government Code, §2254.028(b) states that failure to obtain the finding required by Government Code, §2254.028(a)(3) will cause a major consulting services contract, renewal, amendment, or extension to be void; and add the phrase "if applicable" because some of the sections referenced in this subsection apply to all consulting contracts and some apply only to major consulting services contracts.

The amendments to subsections (c) and (e) make non-substantive changes by deleting the word "then" as unnecessary.

The amendments to subsection (d) delete the entire subsection because the requirements in subsection (d)(1)(A) are not currently authorized by Government Code, Chapter 2254, Subchapter B, and the requirements in subsections (d)(1)(B) and (d)(2) are not needed in this section because they are set forth in Government Code, §2254.031.

The amendments to subsection (e) change "SPD" to "the comptroller" because Government Code, §2254.040 refers to "the comptroller."

The amendments to subsection (f) change the threshold amount for reporting a consulting services contract to the Legislative Budget Board in subsection (f)(1)(B) from "$14,000" to "$50,000"; add the exception that the state agency requesting the payment is not subject to the requirements of subsection (f)(1)(B) if it is a university system or an institution of higher education, to comply with the current provisions of Government Code, §2254.0301(a); change "payer" to "state agency" in subsection (f)(2) to clarify the language of the subsection by using the defined term "state agency"; change "volume and page numbers of the *Texas Register*" to "solicitation ID of the Electronic State Business Daily posting" in subsection (f)(2)(B) to comply with the current provisions of Government Code, §2254.029(a); and delete the reference to Government Code, §2254.033(b) in subsection (f)(2)(A) and §2254.031(a)(2) and (c)(2) in subsection (f)(2)(B) because these provisions no longer exist.

Brad Reynolds, Chief Revenue Estimator, has determined that during the first five years that the proposed amended rule is in effect, the rule: will not create or eliminate a government program; will not require the creation or elimination of employee positions; will not require an increase or decrease in future legislative appropriations to the agency; will not require an increase or decrease in fees paid to the agency; will not increase or decrease the number of individuals subject to the rule's applicability; and will not positively or adversely affect this state's economy.

Mr. Reynolds also has determined that the proposed amended rule would have no significant fiscal impact on the state government, units of local government, or individuals. The proposed amended rule would benefit the public by improving the clarity and implementation of the sections. There would be no significant anticipated economic cost to the public. The proposed amended rule would have no significant fiscal impact on small businesses or rural communities.

You may submit comments on the proposal to Rob Coleman, Director, Fiscal Management Division, at rob.coleman@cpa.texas.gov or at P.O. Box 13528, Austin, Texas 78711. The comptroller must receive your comments no later than 30 days from the date of publication of the proposal in the *Texas Register*.

The amendments are proposed under Government Code, §2254.039(a), which requires the comptroller to adopt rules to implement and administer Government Code, Chapter 2254, Subchapter B, concerning consulting services. The comptroller has given the proposed amendments to §5.54 to the governor

for review and comment as required by Government Code, §2254.039(b).

The amendments implement Government Code, Chapter 2254, Subchapter B concerning consulting services.

§5.54. Consulting Services Contracts.

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

(1) Consulting service--A study conducted for a state agency or advice provided to a state agency under a contract that does not involve the traditional relationship of employer and employee. The term does not include a routine service that is necessary to the functioning of a state agency's programs.

(2) Institution of higher education--Has the meaning assigned by Education Code, §61.003 except the term does not include a public junior college or a community college.

(3) Major consulting services contract--Has the meaning assigned by Government Code, §2254.021(2).

~~[(4) SPD--The Statewide Procurement Division of the comptroller's office.]~~

(4) [~~(5)~~] State agency--Has the meaning assigned by Government Code, §2151.002.

(5) University system--Has the meaning assigned by Education Code, §61.003.

(b) Applicability of this section. This section applies to a consulting service only to the extent Government Code, Chapter 2254, Subchapter B, applies to that service.

(c) Effect of noncompliance with this section or applicable statutes.

(1) If a state agency contracts for a consulting service or renews, amends, or extends a consulting services contract without complying with the requirements of [~~subsection (d) of this section and~~] Government Code, §§2254.028(a)(3), 2254.029 [§§~~2254.029~~], 2254.030, 2254.0301, and 2254.033, if applicable, [~~then~~] the contract, renewal, amendment, or extension is void.

(2) If a contract, renewal, amendment, or extension is void under paragraph (1) of this subsection, [~~then~~] the comptroller may not:

(A) draw a warrant or transmit funds to satisfy an obligation under the contract, renewal, amendment, or extension; or

(B) reimburse a state agency for a payment made under the contract, renewal, amendment, or extension.

(3) If a contract, renewal, amendment, or extension is void under paragraph (1) of this subsection, [~~then~~] a state agency may not make any payments under the contract, renewal, amendment, or extension from any state or federal funds held in or outside the state treasury.

~~[(d) Renewals, amendments, or extensions of consulting services contracts.]~~

~~[(1) A state agency must comply with this paragraph when the agency intends to renew, amend, or extend a major consulting services contract.]~~

~~[(A) If the renewal contract itself is not a major consulting services contract or if the contract after the amendment or extension is no longer a major consulting services contract, then the agency shall file the information required by Government Code, §2254.030 with the secretary of state for publication in the *Texas Register*. The information must be filed not later than the 20th day after either the date the renewal contract is entered into or the date the original contract is amended or extended.]~~

~~[(B) If the renewal contract itself is a major consulting services contract or if the contract after the amendment or extension is still a major consulting services contract, then the agency shall comply with the requirements of Government Code, §2254.028(a) and §2254.029.]~~

~~[(2) A state agency that intends to renew, amend, or extend a consulting services contract that is not a major consulting services contract shall comply with the requirements of Government Code, §2254.028(a) and §2254.029 if the original contract and either the renewal contract, the amendment, or the extension have a reasonably foreseeable value totaling more than $15,000 if the agency is not an institution of higher education or $25,000 if the agency is an institution of higher education.]~~

(d) [~~(c)~~] Procurement of consulting services by the comptroller [~~SPD~~]. If the comptroller [~~SPD~~] procures a consulting service for a state agency under Government Code, §2254.040, the comptroller [~~then SPD~~] must comply with any requirements of this section and Government Code, Chapter 2254, Subchapter B that would apply if the agency were procuring the consulting service directly.

(e) [~~(f)~~] Purchase document requirements.

(1) In addition to the requirements of paragraph (2) of this subsection, the purchase document submitted to the comptroller that requests payment under a contract subject to that paragraph must be supported by the following documentation:

(A) a copy of the original contract and, if the contract has been renewed, amended, or extended, a copy of the renewal, amendment, or extension;

(B) a copy of any written notice provided to the Legislative Budget Board under Government Code, §2254.0301 if the amount of the contract, including any renewal, amendment, or extension, exceeds $50,000 and the state agency requesting the payment is not a university system or an institution of higher education [~~$14,000~~]; and

(C) a statement that the payment complies with Government Code, §§2155.004(a) - (b), 2254.026, 2254.027, and 2254.033.

(2) This paragraph applies when a purchase document is submitted to the comptroller that requests a payment under either a major consulting services contract (or a renewal, amendment, or extension of a major consulting services contract) or a contract that was not originally a major consulting services contract but whose value after renewal, amendment, or extension totals more than $15,000 if the state agency [~~payer~~] is not an institution of higher education or $25,000 if the state agency [~~payer~~] is an institution of higher education. In addition to the requirements of paragraph (1) of this subsection, the document must be supported by the following documentation:

(A) a reference to the solicitation ID [~~volume and page numbers~~] of the Electronic State Business Daily posting [~~*Texas Register*~~] in which the requirements of Government Code, §2254.029 and §2254.030, and, if applicable, Government Code, §2254.028(c) [~~and §2254.033(b)~~] were fulfilled; and

(B) a copy of the governor's finding of fact that the consulting services are necessary if the finding is required by Government Code, §2254.028 [~~§§2254.028, 2254.031(a)(2), or 2254.031(c)(2), or by any combination of those statutes~~].

(3) A state agency that has received the governor's emergency waiver of the requirements of Government Code, Chapter 2254,

Subchapter B must include a copy of the waiver in the supporting documentation for the contract for which the waiver was received.

(4) A state agency shall retain the supporting documentation required by this subsection and provide that documentation to the comptroller as required by §5.51 of this title (relating to Requirements for Purchase Documents).

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 February 7, 2025.

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Victoria North
General Counsel for Fiscal and Agency Affairs
Comptroller of Public Accounts
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For further information, please call: (512) 475-2220