

Title 25. Health Services
Part 1. Department of State Health Services
Chapter 289. Radiation Control
Subchapter E. Registration Regulations
Amendments §§289.230 and 289.234

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission, on behalf of the Department of State Health Services (department), proposes amendments to §289.230, concerning certification of mammography systems and machines used for interventional breast radiography and §289.234 concerning mammography accreditations.

BACKGROUND AND PURPOSE

The amendments to §289.230 implement Senate Bill (SB) 527 and SB 1082, 81st Legislature, Regular Session, 2009, that add clarifying language to Health and Safety Code, Subchapter H, §401.305(c), (e), (f), and (g), relating to the radiation and perpetual care account and Subchapter L, §401.430(f), relating to inspections. In addition, §289.230 revises the manufacturer machine identification information required to be documented; required information from the patient to include the date of birth; and requirements to training received by personnel involved in any aspect of mammography. The amendments to §289.234 are necessary to comply with the four-year review and to correct minor grammatical and typographical errors.

Government Code §2001.039, requires that each state agency review and consider for reoption each rule adopted by that agency pursuant to the Government Code, Chapter 2001 (Administrative Procedure Act). Sections 289.230 and 289.234 have been reviewed and the department has determined that reasons for adopting the sections continue to exist because rules on this subject are needed.

SECTION-BY-SECTION SUMMARY

The amendments to §289.230(b)(4) add language to clarify that a "covered entity" as defined in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its rules at 45 Code of Federal Regulations (CFR), Parts 160 and 164, may be subject to privacy standards governing how information that identifies a patient can be used and disclosed and that failure to follow HIPAA requirements may result in the department making a referral of a potential violation to the United States Department of Health and Human Services.

Sections 289.230(f)(4), (5)(B), and (dd)(3) revise the manufacturer machine identification information required to be documented to ensure more detailed records are maintained.

In §289.230(r)(1)(E) and (2)(E), the current personnel qualifications are deleted and replaced with updated personnel training requirements to ensure that training has met the

recommendations of the American College of Radiology and the United States Food and Drug Administration. In §289.230(r)(3)(E), the mandatory training requirement is deleted.

Section 289.230(t)(1)(A) and (5)(A) revise the required information regarding the patient identification to include the date of birth to ensure a more specific patient identifier.

As a result of Health and Safety Code, §401.305(c), (e), (f), and (g), requirements are added to §289.230(t)(4)(D) regarding retention of clinical images for bankrupt, current, closed or terminated facilities to ensure that patients are provided the opportunity to obtain their mammography film.

Section 289.230(v)(10)(B) regarding surveys, deletes the current requirements for the information contained in the medical physicist's survey report and replaces it with revised clarifying requirements.

Section 289.230(bb) regarding requirements for machines used exclusively for interventional breast radiography, is deleted and relocated to the new §289.230(gg) with revisions to clarify existing requirements. Subsequent subsections 289.230(cc) - (ff) are renumbered to reflect the change.

The record keeping table for the figure in current §289.230(ff)(3) is deleted and replaced with a revised table in §289.230(ee)(3) to update the specific subsections listed.

As a result of Health and Safety Code, §401.430(f), §289.230(ff)(7) is revised to change the time frame in which facilities that receive a severity level I violation shall notify patients on whom the facility performed a mammogram during the period in which the system failed to meet the agency's certification requirements.

Amendments were also made due to Health and Safety Code, §401.430(f) that revise the language in §289.230(ff)(7)(B) to include that the patient consult with the physician regarding having another mammogram performed. These measures were taken to ensure that patients are adequately informed and knowledgeable of their options if the facility fails a certification standards inspection.

Throughout §289.230 and §289.234, minor grammatical, typographical, format and rule reference corrections are made.

FISCAL NOTE

Susan E. Tennyson, Section Director, Environmental and Consumer Safety Section, has determined that for each year of the first five-year period that the sections are in effect, there will be no fiscal implications to state or local governments as a result of enforcing and administering the sections as proposed.

SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Ms. Tennyson has also determined that there will be no adverse economic impact small businesses or micro-businesses required to comply with the amendments as proposed. This was determined by interpretation of the rules that small businesses and micro-businesses will not be required to alter their business practices in order to comply with the sections.

ECONOMIC COST TO PERSONS AND IMPACT ON LOCAL EMPLOYMENT

There are no anticipated economic costs to persons who are required to comply with the sections as proposed. There is no anticipated negative impact on local employment.

PUBLIC BENEFIT

In addition, Ms. Tennyson has also determined that for each year of the first five years the sections are in effect, the public will benefit from adoption of the sections. The public benefit anticipated as a result of enforcing or administering these sections is to ensure continued protection of the public, patients, workers, and the environment from unnecessary exposure to radiation by ensuring that rules are clear and specific.

REGULATORY ANALYSIS

The department has determined that this proposal is not a "major environmental rule" as defined by Government Code, §2001.0225. "Major environmental rule" is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or the public health and safety of a state or a sector of the state.

TAKINGS IMPACT ASSESSMENT

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

PUBLIC COMMENT

Comments on the proposal may be submitted to Barbara J. Taylor, Radiation Group, Policy/Standards/Quality Assurance Unit, Division of Regulatory Services, Environmental and Consumer Safety Section, Department of State Health Services, Mail Code 1987, P. O. Box 149347, Austin, Texas 78714-9347, (512) 834-6770, extension 2010, or by email to Barbaraj.Taylor@dshs.state.tx.us. Comments will be accepted for 30 days following publication of the proposal in the *Texas Register*.

PUBLIC HEARING

A public hearing to receive comments on the proposal will be scheduled after publication in the *Texas Register* and will be held at the Department of State Health Services in Austin, Texas. The meeting date and specific location will be posted on the Radiation Control website (www.dshs.state.tx.us/radiation). Please contact Barbara J. Taylor at (512) 834-6770, extension 2010, or Barbaraj.Taylor@dshs.state.tx.us if you have questions.

LEGAL CERTIFICATION

The Department of State Health Services General Counsel, Lisa Hernandez, certifies that the proposed rules have been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

STATUTORY AUTHORITY

The amendments are authorized by Health and Safety Code, §401.051, which provides the Executive Commissioner of the Health and Human Services Commission with the authority to adopt rules and guidelines relating to the control of radiation; and Government Code, §531.0055, and Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001. Review of the rules implements Government Code, §2001.039.

The amendments affect the Health and Safety Code, Chapters 401, and 1001; and Government Code, Chapter 531.