PROPOSED REGULATION OF THE

STATE BOARD OF HEALTH

LCB File No. R113-12

July 31, 2012

EXPLANATION - Matter in *italics* is new; matter in brackets [omitted material] is material to be omitted.

AUTHORITY: §1, NRS 439.150, 457.065 and 457.183; §§2 and 4-6, NRS 457.065; §3, NRS 457.065 and 457.183.

A REGULATION relating to mammography; revising provisions regarding the posting of a mammographer's certificate and providing a fee for obtaining a duplicate certificate; revising provisions relating to recordkeeping by the operator of a mammography facility; revising provisions regarding information that must be submitted for certification or renewal of certification as a mammographer; establishing requirements for qualification as a mammography instructor; and providing other matters properly relating thereto.

Section 1. NAC 457.295 is hereby amended to read as follows:

457.295 The Health Division shall charge and collect the following nonrefundable fees:

- 1. For the issuance or renewal of a certificate for a machine, \$551.
- 2. For the issuance or renewal of a mammographer's certificate, \$88.
- 3. For the issuance of a duplicate mammographer's certificate for posting at multiple facilities for mammography pursuant to NAC 457.360, \$25.
- **4.** For the issuance or renewal of a certificate to provide training to mammographers pursuant to NAC 457.357, \$100.
 - **Sec. 2.** NAC 457.300 is hereby amended to read as follows:
 - 457.300 The operator of a facility shall:

- 1. Establish and maintain a program of quality assurance in accordance with the provisions of 21 C.F.R. § 900.12 for each machine and all other equipment at the facility used for mammography.
 - 2. Ensure that:
 - (a) The performance of the equipment is monitored;
- (b) The results of monitoring are analyzed to determine if there are any problems requiring correction;
- (c) The necessary corrective action is taken whenever the results of a test for quality assurance indicate that such action is required; and
- (d) If necessary corrective action is taken, the action is taken before any mammography is performed on the patient.
 - 3. Prepare and maintain [a]:
- (a) A list which includes the name of each mammographer who is authorized to operate any machine which is under the operator's control [.]; and
- (b) Copies of the evidence of credentials and training of each mammographer who is authorized to operate any machine which is under the operator's control, including, without limitation, a copy of:
- (1) The mammographer's certification card from the American Registry of Radiologic Technologists, upon which the supervisor of the mammographer has written the date, the notation "original viewed and verified" and the signature of the supervisor.
- (2) The mammographer's certificate, upon which the supervisor of the mammographer has written the date and the signature of the supervisor, along with a notation of either "verified with the Health Division" or "original viewed."

- (3) The mammographer's continuing education certificates of completion, upon which the supervisor of the mammographer has written the date, the notation "original viewed" and the signature of the supervisor.
- (4) Evidence of any other training required by the Health Division or the United States

 Food and Drug Administration, including, without limitation, training in digital

 mammography, upon which the supervisor of the mammographer has written the date, the

 notation "original viewed" and the signature of the supervisor.
- 4. Except as otherwise provided in NAC 457.355, not allow a person who does not hold a mammographer's certificate to operate a machine under the operator's control.
- 5. If the facility for mammography has more than one machine, ensure that a unique machine identifier is included in the information which appears on the edge of the film as it is exposed.
 - 6. Ensure that all quality assurance and quality control records are kept until:
- (a) The next annual inspection has been completed and the Health Division has determined that the facility is compliant; or
- (b) The tests for quality assurance have been performed two additional times at the required frequency and are within the applicable control limits,
- → whichever is longer.
 - **Sec. 3.** NAC 457.350 is hereby amended to read as follows:
- 457.350 1. A person who desires to work as a mammographer in Nevada must be certified in general radiography by the American Registry of Radiologic Technologists, or by another organization approved by the Health Division, and must hold a valid mammographer's certificate.

- 2. A person who desires to work as a mammographer in Nevada may obtain a mammographer's certificate by applying to the [Radiological Health Section of the Bureau of Health Protection Services of the] Health Division. An applicant must:
 - (a) Satisfy the requirements of NRS 457.183; [and]
- (b) Provide documentation satisfactory to the Health Division that the applicant meets the requirements of 21 C.F.R. § 900.12(a)(2) [...];
- (c) Provide the Health Division with the name and address of the applicant's current employer, if any; and
- (d) Sign an attestation that any change in the applicant's employment of during the period of certification will be reported to the Health Division within 7 days after the change and acknowledging that failure to report any such change may result in the suspension or withdrawal of his or her certificate.
- 3. A person who holds a mammographer's certificate and who is employed at more than one facility for mammography must request from the Health Division a duplicate certificate to be posted at each facility where the mammographer is employed, and pay the fee set forth in NAC 457.295 for each such duplicate requested. The Health Division shall provide, upon request from a mammographer and payment of the fee required pursuant to NAC 457.295, a duplicate certificate to be posted at each facility for mammography where the mammographer is employed. A duplicate certificate must be marked by the Health Division as a "Duplicate certificate to be used in place of the original certificate."
 - **Sec. 4.** NAC 457.357 is hereby amended to read as follows:

- 457.357 1. A person who wishes to be certified to provide training to mammographers pursuant to NAC 457.355 must submit an application to the Health Division which is accompanied by the fee set forth in NAC 457.295 and evidence of his or her qualifications.
- 2. The Health Division shall certify a person to provide training to mammographers pursuant to NAC 457.355 if the person complies with subsection 1 and:
- (a) Is certified as a mammographer pursuant to this chapter and chapter 457 of NRS or by any other state;
- (b) Is certified in mammography from the American Registry of Radiologic Technologists; or
 - (c) Meets the requirements of a qualified instructor pursuant to 21 C.F.R. § 900.2.
- 3. A person who wishes to renew his or her certificate to provide training to mammographers pursuant to NAC 457.355 must submit annually an application and the fee for renewal set forth in NAC 457.295 to the Health Division at least 30 days before the expiration of the certificate.
 - **Sec. 5.** NAC 457.360 is hereby amended to read as follows:
 - 457.360 A mammographer shall:
 - 1. Perform each of the mammographer's assigned duties correctly and conscientiously.
- 2. Stand behind a protective barrier whenever X-rays are being produced during mammography.
- 3. Wear on his or her torso the monitoring device assigned to him or her during all working hours.
 - 4. Use optimum techniques of exposure.
 - 5. Use optimum techniques for the processing of images.

- 6. Follow the standing orders and policies for repeated exposures established for the facility *for mammography* at which he or she is employed.
- 7. Correctly determine what views are required, based on a written protocol, and position patients properly.
 - 8. Limit the size of the X-ray field to the area of clinical interest.
 - 9. Instruct each patient clearly to avoid movement by the patient.
- 10. Use appropriate compression with due consideration to the particular circumstances of each case.
- 11. Handle films, cassettes for holding film and other image receptors for mammography carefully to eliminate artifacts.
- 12. Post his or her mammographer's certificate where it can be seen by patients [.] at each facility for mammography where the mammographer is employed.
 - 13. Record his or her full name on the record of each patient.
- 14. Ensure that his or her name or initials are included in the information which appears on the edge of each film as it is exposed.
- 15. Sign or initial the patients' log to indicate each patient upon whom the mammographer performed mammography.
- 16. Indicate, in the space located after his or her signature or initials in the patients' log, the number of films used for each patient.
- 17. Comply with the standards for protection against radiation set forth in NAC 459.320 to 459.664, inclusive, and the requirements of NAC 459.780 to 459.794, inclusive.
- 18. Notify the Health Division of any change in his or her place of employment within 7 business days after any such change.

- 19. Notify the Health Division of any violation of this chapter or chapter 459 of NAC within 30 days after the date on which the mammographer discovers the violation.
 - **Sec. 6.** NAC 457.370 is hereby amended to read as follows:
- 457.370 1. A mammographer who desires to renew his or her mammographer's certificate must submit to the Health Division an application for renewal. The application must:
- (a) Be received by the Division not less than 30 days before the expiration of the certificate; [and]
- (b) Include documentation which establishes that the mammographer possesses a current credential in general radiography [...]; and
 - (c) Include the social security number and date of birth of the mammographer.
- 2. Each mammographer must, as a condition of renewal, furnish to the Health Division evidence that he or she has received not less than 15 hours of continuing medical education in mammography during the immediately preceding 36 months. Continuing education received in compliance with the provisions of this subsection must be approved by the Health Division or a national or regional organization approved by the Health Division, including, without limitation, the American College of Radiology or the American Society of Radiologic Technologists. Evidence of continuing education must include a certificate of completion issued by the sponsoring organization. The certificate must include:
 - (a) The name of the person;
 - (b) The number of hours of credit relating to mammography earned by the person;
 - (c) The dates on which continuing education was received; and
 - (d) The name of the representative of the sponsoring organization who issued the certificate.

- 3. The Health Division will not recognize a mammographer's certification by the American Registry of Radiologic Technologists, or the equivalent, obtained after receipt of his or her mammographer's certificate, as meeting the continuing education requirements of subsection 2.
- 4. Continuing education hours earned through providing instruction or attending a specific course may be counted only once toward the 15 hours of continuing medical education in mammography required by subsection 2, even if the course is taught or attended more than once during the 36-month period.