

SUBCHAPTER 13M - MAMMOGRAM AND PAP SMEAR CERTIFICATION

SECTION .0100 - PAP SMEAR CERTIFICATION

10A NCAC 13M .0101 STATE CERTIFICATION FOR LABORATORIES CONDUCTING PAP SMEARS

- (a) All laboratories evaluating Pap smears shall be state certified by the Division of Health Service Regulation, Department of Health and Human Services, in accordance with this Rule.
- (b) To be state certified, all laboratories shall be licensed under the federal Clinical Laboratory Improvement Act as amended or certified by the Centers for Medicare and Medicaid Services for the specialty of cytology.
- (c) To be state certified, laboratories shall perform Pap smear examinations only on specimens submitted by a health care provider whose scope of practice includes the function of taking Pap smears.
- (d) An application for state certification shall be submitted to the Division of Health Service Regulation listing the name and location of the laboratory requesting certification, the name of the laboratory director and evidence that the laboratory meets the requirements listed in Paragraphs (b) and (c) of this Rule. Laboratories will be notified in writing within 45 days of the receipt of the application that they have been certified or, if certification has been denied, of the reasons for denial.
- (e) State certification must be renewed by a facility when licensing or certification renewal is required by the program that established state certification eligibility pursuant to Paragraph (b) of this Rule.
- (f) If a laboratory's license or certification for one of these programs is suspended or revoked, the laboratory director shall immediately notify the Division of Health Service Regulation and the laboratory's state certification under this Rule shall be revoked. The laboratory may apply for recertification when it can provide evidence that it meets the requirements listed in Paragraphs (a) - (e) of this Rule.
- (g) Appeals of the Division's decisions regarding state certification shall be in accordance with the Administrative Procedures Act, G.S. 150B.

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SECTION .0200 - MAMMOGRAPHY CERTIFICATION

10A NCAC 13M .0201 STATE CERTIFICATION OF SCREENING MAMMOGRAPHY SERVICES

- (a) All facilities performing screening mammograms shall be state certified by the Division of Health Service Regulation, Department of Health and Human Services in accordance with this Rule.
- (b) To be state certified, all equipment used in the performance of screening mammography shall be dedicated to such use by manufacturer's design. Each piece of mammography X-ray equipment, whether located in a fixed or mobile facility, shall be maintained in a safe operating condition and shall be registered and used in accordance with the Rules in 15A NCAC 11.
- (c) To be state certified, all facilities shall be certified by the Centers for Medicare and Medicaid Services or shall be accredited by the American College of Radiology for the performance of mammography screening.
- (d) An application for state certification shall be submitted to the Division of Health Service Regulation listing the name and location of the facility requesting certification, the name of the owner, and evidence that the facility meets the requirements listed in Paragraphs (b) and (c) of this Rule. Facilities shall be notified in writing within 45 days of the receipt of the application that they have been certified or, if certification has been denied, of the reasons for denial.
- (e) State certification must be renewed by a facility when certification or accreditation renewal is required by the program that established state certification eligibility pursuant to Paragraph (c) of this Rule.
- (f) If a facility's certification or accreditation for one of these programs is suspended or revoked, the facility operator shall immediately notify the Division of Health Service Regulation and the facility's state certification under this Rule shall be revoked. The facility may apply for recertification when it can provide evidence that it meets the requirements listed in Paragraphs (a) - (e) of this Rule.
- (g) The North Carolina Medical Care Commission delegates the authority to grant waivers of this Rule to the Division of Health Service Regulation. The Commission, however, shall review all waivers granted at its next regularly scheduled meeting and shall make any revisions to waivers deemed necessary at that time.
- (h) In order to be granted a waiver of this Rule, a facility shall make a request for a waiver in writing to the Division of Health Service Regulation providing the following:

- (1) justification that the rule should not be applied as written, because strict application would cause undue hardship;
- (2) justification that adequate standards assuring early detection of breast cancer and affording protection of health and safety exist and will be met in lieu of the exact requirements;
- (3) justification that the purpose of this Rule is met through equivalent standards affording equivalent protection of health and safety;
- (4) information on the number of screening mammograms performed monthly for the previous six months;
- (5) information proving that there is no state certified facility nearby by identifying the nearest state certified facility and providing information regarding the accessibility of mobile units in the area; and
- (6) a plan for meeting standards necessary for certification, including the time required to meet standards.
 - (i) The Division of Health Service Regulation may grant a waiver to the extent that the factors listed in Paragraph (h) of this Rule are satisfied.

(j) Appeals of the Division's decisions regarding state certification shall be in accordance with the Administrative Procedures Act, G.S. 150B.

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