

LCB File No. T015-98

TEMPORARY REGULATION OF THE STATE BOARD OF HEALTH

NOTICE OF PUBLIC HEARING

NOTICE IS HEREBY GIVEN that the State Health Division will hold public hearing and act on amendments to Nevada Administrative Code (NAC) 445A, 449, and 652. **The hearing is scheduled to begin at 9:00 a.m. on Friday, December 11, 1998, at the Washoe County District Health Department, Ninth and Wells Street, Reno, Nevada.**

OPEN HEART SURGERY

The proposed amendments are needed in order to incorporate practices that have evolved in the area of open heart surgery.

The proposed amendments will eliminate the requirement for two surgeons and provide for the qualification of an allied health professional or senior surgical resident to participate as a member of the surgical team. The amendments will also change the requirement for a clean-up and service area for pump oxygenator equipment. The amendments will change the annual review of the approved hospital.

Adoption of the proposed regulations will result in the following economic impacts:

1. A reduction in costs for the regulated facility, eliminating the cost of out-of-state surveyors for annual inspections.
2. There are no anticipated effects on the public.
3. The cost to the Health Division will include that time required to conduct an annual review.

The proposed regulations do not overlap or duplicate any other Nevada State regulations. The proposed regulations do not include provisions regulated by federal regulations.

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OPEN HEART SURGERY

EXPLANATION – Underlined material is new; material in brackets [] is to be deleted

NOTE: Only those sections being changed are provided in this document.

AUTHORITY: §§2-12, NRS 449.037

Section 1. Chapter 449 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 5 inclusive, of this regulation.

Sec. 2. “Approval” means the approval granted by the health division to a hospital authorizing the hospital to perform open-heart surgery.

Sec. 3. “Approved hospital” means a hospital that has obtained approval from the health division to perform open-heart surgery.

Sec. 4. “Cardiac surgery” means an operation performed on the heart or on the blood vessels connected to the heart in which access to the area of interest is provided by means of an incision in the wall of the thorax or for which the use of a heart-lung bypass machine is required.

Sec. 5. “Open-heart surgery” means any cardiac surgery requiring the use of a heart-lung bypass machine.

Sec. 6. NAC 449.612 is hereby amended to read as follows:

NAC 449.612 As used in NAC 449.612 to 449.61256, inclusive, and sections 2 to 5, inclusive, of this regulation, unless the context otherwise requires [:

1. “Approval” means the approval granted by the health division to a hospital authorizing the hospital to perform open-heart surgery.
2. “Approved hospital” means a hospital that has obtained approval from the health division to perform open-heart surgery.
3. “Cardiac surgery” means an operation performed on the heart or on the blood vessels connected to the heart in which access to the area of interest is provided by means of an incision in the wall of the thorax or for which the use of a heart-lung bypass machine is required.
4. “Open-heart surgery” means any cardiac surgery requiring the use of a heart-lung bypass machine.] , the words and terms defined in sections 2 to 5, inclusive, of this regulation have the meanings ascribed to them in those sections.

Sec. 7. NAC 449.61204 is hereby amended to read as follows:

449.61204 1. The application for approval must include a statement describing:

- (a) The qualifications of the [hospital’s] personnel of the hospital to perform open-heart surgery;
- (b) The facilities and equipment to be used in performing open-heart surgery; and
- (c) The manner in which the [hospital’s] facilities and personnel of the hospital meet or exceed the requirements of NAC 449.612 to 449.61256, inclusive [.] , and sections 2 to 5, inclusive, of this regulation.

2. The application must contain a statement by the chief of cardiac service for the hospital that the hospital has the facilities, equipment, personnel, staffing, policies and procedures required to perform surgeries at or above the rate required by NAC 449.61214.

3. The application must contain a statement by the chief operating officer of the hospital that the hospital is committed to maintaining the support personnel and equipment required to perform surgeries at or above the rate required by NAC 449.61214.
4. [If a hospital is required, pursuant to NRS 439A.100, to obtain the approval of the director of the department of human resources to provide services for open-heart surgery, a copy of that letter of approval must be submitted with the application.
- 5.] The health division shall prescribe a uniform form of application.

Sec. 8. NAC 449.61208 is hereby amended to read as follows:

NAC 449.61208 The site inspection team:

1. Must be composed of a cardiothoracic surgeon, a cardiologist, a cardiac intensive care nurse, an administrator of a hospital [currently performing] at which open-heart surgery is currently performed and a [physician] surveyor of health facilities from the health division.
2. Shall review the [hospital's] service of the hospital for open-heart surgery and make findings concerning:
 - (a) The adequacy of the [hospital's] equipment of the hospital for use in such surgery.
 - (b) Whether the personnel of the hospital meet the requirements of NAC 449.612 to 449.61256, inclusive[.], and sections 2 to 5 , inclusive, of this regulation.
 - (c) The adequacy of the size of the staff available to perform open-heart surgery at the hospital.
 - (d) The adequacy and appropriateness of the policies and procedures adopted by the hospital relating to the service.

(e) Whether the hospital has sufficient facilities, staff and equipment to perform open-heart surgeries at the rate required by NAC 440.61214.

Sec. 9. NAC 449.61212 is hereby amended to read as follows:

449.61212 1. Within 15 working days after it receives the findings of the site inspection team, the health division shall approve or notify the hospital of its intention to disapprove the application.

2. Unless it is revoked or suspended pursuant to NAC 449.61256, the approval of an application is valid for 5 years.

3. **[At]** Not later than 6 months before the end of the period of approval, the hospital must submit a new, complete application to the health division if the service is to be continued. The hospital must be reinspected by a site inspection team as provided in NAC 449.61208.

Sec. 10. NAC 449.61218 is hereby amended to read as follows:

449.61218 Composition of surgical team; participation by qualified nurses.

1. A surgical team assigned to each open-heart surgery at an approved hospital must be composed of **[at least two cardiac]** a primary cardiovascular surgeon[s, or] and at least one **[cardiac surgeon and one vascular surgeon]** of the following individuals, as determined by the clinical judgment of the primary cardiovascular surgeon:

(a) A cardiovascular, vascular or general surgeon; or

(b) A person who is authorized to assist in the surgery by the medical staff of the approved hospital, or

(c) A senior surgical resident.

2. The [**cardiac**] primary cardiovascular surgeon[s] must be certified or eligible for certification by the American Board of Thoracic Surgery.
3. A person who is authorized to assist in the surgery pursuant to paragraph 1(b) must be accorded the privileges of a member of the allied health professions by the medical staff of the approved hospital. The medical staff shall:
- (a) Establish criteria for authorizing persons to assist in open-heart surgery that are consistent with current professional standards; and
- (b) Reevaluate those criteria at least once every 2 years.
4. A senior surgical resident participating as a member of the open-heart surgery team pursuant to paragraph 1(c) must be enrolled in a program accredited by the Accreditation Council on Graduate Medical Education.
5. [2.] A team of open-heart surgical nurses whose training has been verified by the head nurse shall participate in each operation.
6. As used in this section, “medical staff” means the medical staff organized by an approved hospital pursuant to NAC 449.358.

Sec. 11. NAC 449.61228 is hereby amended to read as follows:

449.61228 1. Each operating room designated or available for open-heart surgery must be equipped with:

- (a) A heart-lung bypass machine.
- (b) Proper suction and plumbing outlets for heat exchangers for the heart-lung bypass machine.
- (c) An adequate supply of electrical power, including, without limitation, standby emergency electrical power.

- (d) Surgical instruments.
- (e) A device to conserve blood.
- (f) An electronic warmer for blood.
- (g) Monitors to review the electrocardiogram and the pressure in two channels of blood flow.
- (h) Operating lights which are sufficiently bright to illuminate the inside of body cavities[,] and sufficiently maneuverable to illuminate two operating fields on a patient simultaneously.
- (i) A defibrillating apparatus.

2. The operating room must have available:

- (a) A complete set of pump oxygenator equipment. [with a clean-up and service area for the equipment.]
- (b) Facilities and appropriate support personnel for the use of an intra-aortic balloon.

3. Each operating room designated for open-heart surgery must be provided with the number of surgical nurses, technicians and ancillary personnel needed to staff the equipment and stations required in performing general surgical operations.

Sec. 12. NAC 449. 6125 is hereby amended to read as follows:

449.6125 [1. The health division] A surveyor of health facilities shall conduct [an on-site inspection] a review of each approved hospital annually to verify that the hospital is complying with the provisions of NAC 449.612 to 449.61256, inclusive [.] and sections 2 to 5 inclusive, of this regulation.

[2. The site inspection team for the annual inspection must be composed of a cardiologist, a cardiac surgeon and a physician from the health division. The team shall conduct the inspection in the manner provided in NAC 449.61208.]