

**ADOPTED REGULATION OF
THE STATE BOARD OF HEALTH**

LCB File No. R107-98

Effective March 18, 1999

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

AUTHORITY: §§2-13, 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:

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 which has obtained approval from the health division to perform open-heart surgery.

3. “Cardiac surgery” means any 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 which requires the use of a heart-lung bypass machine.

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 the letter of approval must be submitted with the application.

5.] *The application must indicate whether the hospital will, if its application is approved, perform open-heart surgery on infants or children.*

5. The health division shall prescribe a uniform form of application.

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

449.61208 The site inspection team:

1. Must be composed of [a] :

(a) A cardiothoracic surgeon [, a cardiologist, a] ;

(b) A cardiologist;

(c) A cardiac intensive care nurse [, an] ;

(d) An administrator of a hospital [currently performing] at which open-heart surgery [and a physician] is currently performed;

(e) A surveyor of health facilities from the health division [.] ; and

(f) *If the hospital indicated in its application that it would perform open-heart surgery on infants or children, a pediatric cardiologist.*

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 449.61214.

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] *An approval issued pursuant to this section is valid until* it is revoked or suspended pursuant to NAC 449.61256 . [, the approval of an application is valid for 5 years.

3. *At 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.]*

3. *A hospital that ceases to perform open-heart surgeries shall notify the health division in writing within 30 days after the last surgery is performed. If a hospital has notified the health division in writing that it is ceasing to perform open-heart surgeries and subsequently decides that it desires to begin performing open-heart surgery again, it must reapply for approval*

pursuant to the provisions of NAC 449.612 to 449.61256, inclusive, and sections 2 to 5, inclusive, of this regulation.

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

449.61218 1. A surgical team assigned to *each* open-heart surgery at an approved hospital must be composed of [*at least two cardiac surgeons, or at least one cardiac surgeon and one vascular surgeon. The cardiac surgeons*] *a cardiovascular surgeon who will be the primary surgeon and at least one other person chosen by the primary surgeon who must be a:*

(a) Cardiovascular surgeon;

(b) Vascular surgeon;

(c) General surgeon;

(d) Person who is authorized by the medical staff of the approved hospital to assist in such surgeries; or

(e) A senior surgical resident who is enrolled in a medical training program accredited by the Accreditation Council for Graduate Medical Education.

2. *The primary surgeon* must be certified or eligible for certification by the American Board of Thoracic Surgery. [*The vascular surgeons must be certified or eligible for certification by the American Board of Surgery.*

2.] 3. *A person who is authorized to assist in the surgery pursuant to paragraph (d) of subsection 1 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 team of open-heart surgical nurses whose training has been verified by the head nurse shall participate in each operation.

5. *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**] *Unless the hospital has notified the health division that it has ceased to perform open-heart surgeries, a surveyor of health facilities from the* health division shall [conduct an on-site inspection of] *review* each approved hospital annually to verify that the hospital is complying with the provisions of NAC 449.612 to 449.61256, inclusive [.

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.] , and sections 2 to 5, inclusive, of this regulation.*

Sec. 13. NAC 449.61254 is hereby amended to read as follows:

449.61254 1. If the [inspection] *review conducted pursuant to NAC 449.6125* discloses that the hospital is not in full compliance with the provisions of NAC 449.612 to 449.61256, inclusive, *and sections 2 to 5, inclusive, of this regulation*, or if a facility's adjusted rate of mortality, after considering the factors enumerated in NAC 449.61252, is considered excessive, the health division *may, at the expense of the hospital, require:*

(a) *A second review; or*

(b) *An on-site inspection,*

conducted by one or more of the persons specified in NAC 449.61208. When the health division has completed its final review or inspection pursuant to this subsection, it shall notify the hospital in writing of the violations and the recommendations [of the site inspection team] for

improvements in the hospital's service [.] *made by the person or persons who conducted the review or inspection pursuant to this subsection.*

2. Within 30 days after it receives the notice, the hospital shall reply to the health division in writing, indicating the measures to be taken to achieve compliance with the provisions of NAC 449.612 to 449.61256, inclusive, *and sections 2 to 5, inclusive, of this regulation* and to carry into effect the recommendations [*of the site inspection team.*] *made by the person or persons who conducted the review or inspection pursuant to subsection 1.*

3. If the health division determines that the hospital's plan is satisfactory, all of the corrective actions proposed by the hospital must be completed within 90 days after the health division has received the plan. After that time, the health division may require another [*inspection*] *review* of the hospital [*by a site inspection team.*] *pursuant to NAC 449.6125 or a review or inspection conducted pursuant to subsection 1 of this section.*