## PROPOSED REGULATION OF

## THE STATE BOARD OF HEALTH

## LCB File No. R107-98

July 23, 1998

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 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 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 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 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 1. [A] Except as otherwise provided in subsection 2, the surgical team assigned to each open-heart surgery performed at an approved hospital must be composed of at least [two]:
  - (a) Two cardiac surgeons [, or at least one]; or
  - (b) One cardiac surgeon and one vascular or general surgeon.

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

- 2. The second cardiac surgeon specified in paragraph (a) of subsection 1 or the vascular or general surgeon specified in paragraph (b) of subsection 1 is not required to be present in the operating room for the duration of the operation unless:
- (a) In his clinical judgment, the primary cardiac surgeon determines that the presence of the second surgeon is necessary; or
- (b) The rules or regulations established by the medical staff of the approved hospital require the presence of the second surgeon.
- 3. If a second cardiac surgeon or a vascular or general surgeon is not present in the operating room for the duration of the surgery pursuant to subsection 2, a person who is authorized to assist in the surgery by the medical staff of the approved hospital must be present in the operating room for the duration of the surgery.
- 4. A person who is authorized to assist in the surgery pursuant to subsection 3 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.
- 5. 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 449.61246 is hereby amended to read as follows:

449.61246 A registry must be maintained at an approved hospital and used for recording the results of open-heart surgery for each patient. This registry must include or indicate, for each such patient:

- 1 His patient identification number.
- 2. His race.
- 3. His age.
- 4. His sex.
- 5. Any history of hypertension, smoking, diabetes mellitus, cerebrovascular disease, coronary bypass, myocardial infraction, chronic obstructive pulmonary disease or renal disease.
  - 6. The period during which the surgery is performed.
  - 7. The period during which the heart-lung bypass machine is used.
  - 8. The period during which a crossclamp is in place.
  - 9. His ASA acquity classification.
  - 10. His New York Heart Association functional classification.
  - 11. A record of any angioplasty performed or thrombolytic therapy.
  - 12. A record of any use of an intra-aortic balloon pump.
  - 13. Whether he is an elective, emergency or transfer case.
  - 14. The number of [days] *hours* he is intubated.
  - 15. The number of [days] *hours* he is in the cardiac surgery unit.
  - 16. The length of his hospital stay.

- 17. The location to which he is discharged.
- 18. A record of his 30-day follow-up examination.
- 19. A record of his ventricular function (ejection fraction) [.] before and after surgery.
- 20. The description of the surgical procedure and, if applicable, the number of vessels involved and the type of graft (mammary or saphenous).
  - 21. A record of any complications, including [:], without limitation:
  - (a) Additional surgery for bleeding;
  - (b) Perioperative myocardial infarction;
  - (c) Infections of the sternum, leg or intra-aortic balloon pump site; or
  - (d) Stroke.
  - **Sec. 13.** NAC 449.6125 is hereby amended to read as follows:
- 449.6125 1. The health division shall conduct an on-site inspection 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] *surveyor of health facilities* from the health division. The team shall conduct the inspection in the manner provided in NAC 449.61208.