

LCB File No. R107-98

PROPOSED REGULATION OF THE HEALTH DIVISION

(Workshops for this proposed regulation were held in Reno and Las Vegas on July 2, 1998. It will come before the State Board of Health on August 7, 1998.)

CHAPTER 449

OPEN-HEART SURGERY

Explanation – underlined matter is new; matter in brackets [] is material to be deleted.

449.61204 Form and contents of application for approval to provide service.

1. The application for approval must include a statement describing:
 - (a) The qualifications of the hospital's personnel 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 meet or exceed the requirements of NAC 449.612 to 449.61256, inclusive.
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.

5. An application for approval for open-heart surgery must be accompanied by an application fee of \$1,500.

449.61208 Composition and duties of site inspection team. 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 open-heart surgery and a [physician] health facilities surveyor from the health division.

2. Shall review the hospital's service for open-heart surgery and make findings concerning:

(a) The adequacy of the hospital's equipment for use in such surgery.

(b) Whether the personnel of the hospital meet the requirements of NAC 449.612 to 449.61256, inclusive.

(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.

449.6121 Hospital to pay costs of inspection. The costs incurred in connection with any inspection or review of registry data required by the provisions of NAC 449.612 to 449.61256, inclusive, by a person who is not an employee of the health division, must be paid by the hospital affected

449.61212 Approval or denial of application; period of approval; subsequent application and inspection.

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 prior to 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. As part of the application renewal process the collective registry data specified at NAC 449.61246 must be reviewed by an independent party, selected by the Health Division, for assessment of morbidity and mortality outcomes if:

(a) the review determines deficiencies exist, or there are significant variances in patient outcomes for cardiac and open-heart surgery, or

(b) in the previous 5 years, the annual on-site inspection determined deficiencies existed, or there were significant variances in patient outcomes for cardiac and open-heart surgery, [T]the hospital must be reinspected by a site inspection team as provided in NAC 449.61208.

449.61218 Composition of surgical team; participation by qualified nurses.

1. Except as otherwise provided in subsection 2, [A] a surgical team assigned to 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 to ensure adequate and continuous perioperative care as well as assistance in the operating room. The cardiac surgeons 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. The second surgeon is not required to

be present in the operating room for the duration of the surgical case, but must be present based on the clinical judgement of the primary cardiac surgeon and consistent with the rules and regulations established by the medical staff of the hospital, organized in accordance with NAC 449.358.

2. If the second qualified cardiac surgeon or vascular surgeon is not present in the operating room during the surgery, the surgical team must include an assistant who holds current allied health staff privileges that a qualified surgeon on the open-heart surgical team. The criteria must be consistent with current professional standards. The medical staff shall reevaluate the criteria no less than every two years.

[2.]3. A team of open-heart surgical nurses whose training has been verified by the head nurse shall participate in each operation.

449.61228 Operating rooms: Equipment and staff.

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 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.

449.61246 Maintenance of registry to record results for each patient. A registry must be maintained at an approved hospital and used for recording the results of open- heart surgery for each patient. The registry data must be collected and maintained in accordance with standards established by the Health Division. Standards shall ensure the ability to conduct aggregate and interagency data comparisons. 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 acuity 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 he is intubated.
15. The number of days 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).
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:
 - (a) Additional surgery for bleeding;
 - (b) Peri-operative myocardial infarction;
 - (c) Infections of the sternum, leg or intra-aortic balloon pump site; or
 - (d) Stroke.

Approved hospitals must transmit their registry data to the Health in a format and at intervals established by the Health Division.

449.6125 Annual on-site inspection: General requirements.

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.

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**] shall be composed of health facilities surveyors from the Health Division and adjunct staff as deemed necessary by the Health Division. The team shall conduct the inspection in the manner provided in NAC 449.61208.

3. If the site inspection team determines deficiencies exist, or there are significant variances in patient outcomes for cardiac and open-heart surgery, a site inspection team composed of a cardiologist, a cardiac surgeon and a health facilities surveyor from the health division shall conduct an assessment of the program. The team shall conduct the inspection in the manner provided in NAC 449.61208.

449.61252 Annual on-site inspection: Assessment of rate of mortality.

1. As a part of the annual inspection of each approved hospital, the health division shall perform a detailed review of the patient files relating to all mortalities and morbidity at the hospital.

2. In assessing whether a hospital's adjusted rate of mortality and morbidity is acceptable for the purposes of NAC 449.612 to 449.61256, inclusive, the inspection team shall fully consider, among other things, the age and sex of the patient, the acuity of the patient's illness and the information contained in the registry maintained pursuant to NAC 449.61246.

3. As used in this section, "mortality" means the death of any patient who dies within 30 days after undergoing open-heart surgery. (Added to NAC by Bd. of Health, eff. 8-31-89)

449.61254 Annual on-site inspection: Notification of violations and recommendations for improvement; corrective action by hospital.

1. If the inspection discloses that the hospital is not in full compliance with the provisions of NAC 449.612 to 449.61256, inclusive, or if a facility's adjusted rate of mortality and morbidity, after considering the factors enumerated in NAC 449.61252, is considered excessive, the health division shall notify the hospital in writing of the violations and the recommendations of the site inspection team for improvements in the hospital's service.

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 to carry into effect the recommendations of the site inspection team.

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 of the hospital by a site inspection team.

4. The health division may require the approved hospital to acquire the consultation services of an individual or agency, approved by the health division, which provides Cardiovascular and Open-heart Surgery peer review.