

**PROPOSED REGULATION OF THE  
STATE BOARD OF HEALTH**

**LCB FILE NO. R141-26I**

**The following document is the initial draft regulation proposed  
by the agency submitted on 06/18/2026**

## **Open-Heart Surgery**

### **Proposed Amendments to NAC 449.612**

#### **Draft**

The proposed amendments are needed in order to modernize and strengthen Nevada's oversight of open heart surgery and adult cardiac catheterization services and to incorporate practices that have evolved in the areas of cardiac surgery, emergency readiness and interventional cardiology. Advances in these fields have significantly changed how hospitals provide cardiac care, and the current regulations do not reflect these developments.

The proposed amendments are needed to update Nevada's standards by shifting from a strictly volume based model to a framework that evaluates hospitals based on quality, safety, risk adjusted outcomes and geographic access to care. Modern cardiac oversight must account for the fact that patient safety is determined not only by procedural volume, but also by clinical outcomes, continuous specialty coverage, and a hospital's ability to respond to emergent cardiac events on a 24hour basis.

The proposed amendments will establish clear definitions and requirements for Level II and Level III adult cardiac catheterization services. These definitions are necessary to ensure consistent expectations across hospitals regarding emergency transfer protocols, safety standards, credentialing criteria and participation in nationally recognized clinical registries. These components are essential for monitoring operator and institutional performance and for ensuring safe, appropriate delivery of diagnostic and interventional cardiac procedures.

The proposed amendments also strengthen requirements for uninterrupted 24hour specialty coverage for cardiac services, provide for performance based review of hospitals with low procedural volumes but acceptable clinical outcomes and update inspection requirements to include annual offsite data reviews and mandatory triennial onsite inspections. These changes create a more sustainable oversight model for the Division and ensure consistent monitoring, especially given prior challenges associated with staffing shortages, onboarding of new survey staff and inspection backlogs.

The proposed amendments needed to ensure that cardiac services in Nevada remain safe, reliable and aligned with national standards, and to preserve reasonable geographic access to lifesaving cardiac care for residents across the state. The proposed regulations do not duplicate or overlap with other Nevada state regulations and do not include provisions governed by federal law.

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

**NAC 449.612 Definitions.** (NRS 449.0302) As used in NAC 449.612 to 449.61256, inclusive, unless the context otherwise requires, the words and terms defined in NAC 449.612011 to 449.612017, inclusive, have the meanings ascribed to them in those sections.

(Added to NAC by Bd. of Health, eff. 8-31-89; A 8-1-91; R107-98, 3-18-99)

**NAC 449.612011 “Approval” defined.** (NRS 449.0302) “Approval” means the approval granted by the Division to a hospital authorizing the hospital to perform open-heart surgery.

(Added to NAC by Bd. of Health by R107-98, eff. 3-18-99)

**NAC 449.612012 “Approved hospital” defined.** (NRS 449.0302) “Approved hospital” means a hospital that has obtained approval from the Division to perform open-heart surgery.

(Added to NAC by Bd. of Health by R107-98, eff. 3-18-99)

**NAC 449.612014 “Cardiac surgery” defined.** (NRS 449.0302) “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.

(Added to NAC by Bd. of Health by R107-98, eff. 3-18-99)

**NAC 449.612017 “Open-heart surgery” defined.** (NRS 449.0302) “Open-heart surgery” means any cardiac surgery requiring the use of a heart-lung bypass machine.

(Added to NAC by Bd. of Health by R107-98, eff. 3-18-99)

***NAC 449.612018 “Level I cardiac catheterization service” defined.** (NRS 449.0302) “Level I cardiac catheterization service” or “level I service” means an adult cardiac catheterization service located in a hospital without an on-site open-heart surgery service that provides only diagnostic cardiac catheterization procedures on an organized regular basis.*

***NAC 449.612019 “Level II cardiac catheterization service” defined.** (NRS 449.0302) “Level II cardiac catheterization service” means an adult cardiac catheterization service located in a hospital without an on-site open-heart surgery service that provides diagnostic and authorized therapeutic cardiac catheterization procedures on an organized and regular basis.*

***NAC 449.61200 “Level III cardiac catheterization service” defined.** (NRS 449.0302) “Level III cardiac catheterization service” means an adult cardiac catheterization service located in a hospital with an on-site open-heart surgery service that provides all levels of diagnostic and therapeutic cardiac catheterization procedures authorized by the Division.*

*NAC 449.61201 “Receiving service” defined. (NRS 449.0302) “Receiving service” means a licensed hospital that provides open-heart surgery services and that is a party to a written transfer protocol with a Level II cardiac catheterization service for emergency medical or surgical management.*

**NAC 449.61202 Prerequisites to initial provision of service. (NRS 449.0302)** A hospital that desires to provide a new service for the performance of open-heart surgery must make application to the Division requesting approval of the service. A hospital shall not provide such a service until the Division has given its approval in writing.

(Added to NAC by Bd. of Health, eff. 8-31-89)

**NAC 449.61204 Form and contents of application for approval to provide service. (NRS 449.0302)**

1. The application for approval must include a statement describing:
  - (a) The qualifications of the 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 facilities and personnel of the hospital 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. The application must indicate whether the hospital will, if its application is approved, perform open-heart surgery on infants or children.
5. The Division shall prescribe a uniform form of application.

(Added to NAC by Bd. of Health, eff. 8-31-89; A by R107-98, 3-18-99)

**NAC 449.61206 Notification of applicant upon review of application; site inspection required. (NRS 449.0302)**

1. Within 10 days after it receives an application for approval from a hospital, the Division shall notify the hospital, in writing, whether the application is complete. If the application is incomplete, the Division shall inform the applicant which parts of the application are deficient. If

the application is complete, the Division shall notify the applicant of the composition of the site inspection team, the date of the team's visit to the site and the scheduled date for the team to present its findings to the Division. The Division shall notify the applicant of any changes in this timetable as they occur.

2. The application must not be approved by the Division until the findings of the site inspection team verify that the hospital complies with the requirements of [NAC 449.612](#) to [449.61256](#), inclusive.

(Added to NAC by Bd. of Health, eff. 8-31-89)

**NAC 449.61208 Composition and duties of site inspection team.** ([NRS 449.0302](#)) The site inspection team:

1. Must be composed of:

(a) A cardiothoracic surgeon;

(b) A cardiologist;

(c) A cardiac intensive care nurse;

(d) An administrator of a hospital at which open-heart surgery is currently performed;

(e) A surveyor of health facilities from the 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 service of the hospital for open-heart surgery and make findings concerning:

(a) The adequacy of the 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.

(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](#).

(Added to NAC by Bd. of Health, eff. 8-31-89; A by R107-98, 3-18-99)

*3. In evaluating an application or conducting a review of an approved hospital, the site inspection team shall consider, in addition to the matters otherwise required by this section:*

- (a) the hospital's systems for quality assessment and performance improvement;*
- (b) the hospital's enrollment and participation in a nationally recognized clinical outcomes registry for adult cardiac surgery;*
- (c) the hospital's capacity to provide emergency surgery and postoperative intensive care on a continuous basis; and*
- (d) the extent to which the service is necessary to preserve reasonable geographic access to open-heart surgery within the hospital's referral region."*

**NAC 449.6121 Hospital to pay costs of inspection. ([NRS 449.0302](#))** The costs incurred in connection with any inspection required by the provisions of [NAC 449.612](#) to [449.61256](#), inclusive, must be paid by the hospital affected.

(Added to NAC by Bd. of Health, eff. 8-31-89)

**NAC 449.61212 Approval or denial of application; period of validity of approval; cessation of performance of surgeries. ([NRS 449.0302](#))**

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

2. An approval issued pursuant to this section is valid until it is revoked or suspended pursuant to [NAC 449.61256](#).

3. A hospital that ceases to perform open-heart surgeries shall notify the Division in writing within 30 days after the last surgery is performed. If a hospital has notified the 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.

(Added to NAC by Bd. of Health, eff. 8-31-89; A by R107-98, 3-18-99)

*4. If a hospital experiences a gap in the continuous specialty coverage required by NAC 449.61218, 449.6122, 449.61222 and 449.61224 that exceeds 48 consecutive hours or more than 10 cumulative days in a calendar year, the hospital shall immediately notify the Division. Upon receipt of such notice, the hospital's authority to perform elective open-heart surgery is suspended until the Division verifies restoration of the required coverage. During the period of suspension, the hospital may provide only emergency stabilization and any emergency procedure expressly authorized by the Division."*

**NAC 449.61214 Amount of surgery required following approval; *conditional exemptions based on clinical outcomes and regional access.*** (NRS 449.0302) *Except as otherwise provided in subsection 2, after approval of a service for open-heart surgery is granted, an approved hospital must maintain sufficient case volume, staffing, equipment, and clinical support to ensure the safe and effective provision of open-heart surgery [such surgeries must be performed in an approved hospital] at the following rates:*

1. Not less than 80 operations during the first 12 months after approval.
2. Not less than 150 operations during the second 12-month period after approval.
3. Not less than 200 operations during the third and each succeeding 12-month period after approval.

*2. The Division shall not deny, suspend, or revoke approval solely because an approved hospital fails to perform the specified number of operations required by subsection 1 during any 12-month period if the hospital demonstrates, in a form prescribed by the Division, that:*

*(a) The hospital participates in a nationally recognized clinical outcomes registry for adult cardiac surgery, including, without limitation, the Society of Thoracic Surgeons (STS) National Database or its successor, or an equivalent registry approved by the Division, in accordance with NAC 449.61246 and NAC 449.6125;*

*(b) The hospital's risk-adjusted clinical outcomes are acceptable to the Division when compared with applicable national benchmarks based on risk-adjusted mortality and major morbidity measures recognized by the registry;*

*(c) The hospital maintains continuous capacity to perform emergency open-heart procedures on a 24-hour-a-day, 7-day-a-week basis;*

*(d) The hospital maintains qualified surgeons, anesthesiologists, perfusionists, nurses, and support personnel sufficient to provide services safely;*

*(e) The hospital operates a functional internal peer and program review framework to track surgeon-specific data and safety metrics as required under NAC 449.61253; and*

*(f) Continued operation of the service is reasonably necessary to preserve timely geographic access to care for residents of the hospital's referral region.*

*3. In determining whether an approved hospital that does not meet any volume or quality benchmark established by the Division may continue to operate, the Division shall conduct an evaluation and consider, without limitation:*

- (a) The hospital's risk-adjusted mortality and major morbidity results;*
- (b) Procedure-specific and surgeon-specific volumes;*
- (c) Travel time and transport barriers, including winter weather passes or prolonged transport vectors, affecting patients in the hospital's referral region;*
- (d) The availability of alternative approved hospitals within the referral region;*
- (e) Transfer capability, emergency coverage, and continuity of postoperative care; and*
- (f) The development, submission, and execution of any corrective action plan approved by the Division to address identified quality deficiencies.*

(Added to NAC by Bd. of Health, eff. 8-31-89)

**NAC 449.61216 Provision of patient with preoperative instruction. ([NRS 449.0302](#))**

On specific orders from the patient's physician, a cardiac surgical nurse shall provide each nonemergent cardiac surgical patient with preoperative instruction concerning the proposed surgical procedure and the general course of his or her treatment.

(Added to NAC by Bd. of Health, eff. 8-31-89)

**NAC 449.61218 Surgical team: Composition; privileges and qualifications of members; participation of qualified nurses. ([NRS 449.0302](#))**

1. A surgical team assigned to each open-heart surgery at an approved hospital must be composed of 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.

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](#).

(Added to NAC by Bd. of Health, eff. 8-31-89; A by R107-98, 3-18-99)

*6. An approved hospital shall maintain documented, verifiable proof of uninterrupted on-call specialist coverage, 24 hours a day, 7 days a week and 365 days a year, for the roles identified in subsection 1 and in NAC 449.6122, 449.61222 and 449.61224.*

**NAC 449.6122 Qualifications of anesthesiologist. ([NRS 449.0302](#))** Anesthesia during open-heart surgery at an approved hospital must be administered by an anesthesiologist who:

1. Is certified by or who is eligible for certification by the American Board of Anesthesiologists; and

2. Has special training or experience in the administration of anesthesia in open-heart surgery.

(Added to NAC by Bd. of Health, eff. 8-31-89)

**NAC 449.61222 Qualifications of nurse in charge of service. ([NRS 449.0302](#))** The registered nurse in charge of the service for open-heart surgery at an approved hospital must:

1. Have not less than 2 years of operating room nursing experience and not less than 1 year of current experience in open-heart surgery; and

2. Be permanently assigned to that service.

(Added to NAC by Bd. of Health, eff. 8-31-89)

**NAC 449.61224 Perfusion team: Use required; qualifications; approval of members by surgeon of record. ([NRS 449.0302](#))**

1. An approved hospital shall use a perfusion team, which must include a senior perfusionist who is responsible for the supervision of all perfusion services provided by the team.

2. The senior perfusionist must be certified by the American Board of Cardiovascular Perfusionists. The other perfusionists of the heart-lung bypass machine must be certified or eligible for certification by the Board.

3. The senior perfusionist and the other perfusionists must:

(a) Be trained in:

- (1) Aseptic techniques required in an operating room;
- (2) Perfusion physiology; and
- (3) The use of monitoring equipment; and

(b) Have a general understanding of commonly performed cardiac surgical procedures.

4. The cardiac surgeon of record shall approve each perfusionist involved with the surgeon's patients as being competent to operate the heart-lung bypass machine properly before allowing that person to operate the machine during open-heart surgery.

(Added to NAC by Bd. of Health, eff. 8-31-89)

**NAC 449.61226 Operating rooms: General requirements. ([NRS 449.0302](#))**

1. An approved hospital shall maintain two fully equipped operating rooms, one dedicated to and another available for services for open-heart surgery. Each operating room must have a minimum clearance of 400 square feet, exclusive of fixed cabinets and built-in shelves. Entry to the operating rooms must be limited to persons participating in the service.

2. The ventilation and temperature control systems of each operating room must be able to provide a minimum of 15 air changes per hour in the operating room and maintain the air temperature between 70°F and 75°F, with a relative humidity between 50 and 60 percent.

(Added to NAC by Bd. of Health, eff. 8-31-89)

**NAC 449.61228 Operating rooms: Equipment and staff. ([NRS 449.0302](#))**

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.

(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.

(Added to NAC by Bd. of Health, eff. 8-31-89; A by R107-98, 3-18-99)

**NAC 449.6123 Intensive care facility: General requirements. ([NRS 449.0302](#))**

1. An approved hospital shall maintain an intensive care facility within the hospital. The facility must:

(a) Have accommodations which can isolate patients;

(b) Have a sufficient system for controlling temperature to maintain comfortable conditions for the patients and members of the hospital's staff; and

(c) Be equipped to provide continuous electrocardiographic monitoring of each patient in the facility.

2. Each bed in the intensive care facility must be equipped with:

(a) Outlets for suction and oxygen; and

(b) Adequate lighting for illuminating minor surgical procedures.

(Added to NAC by Bd. of Health, eff. 8-31-89)

**NAC 449.61232 Intensive care facility: Staff. ([NRS 449.0302](#))**

1. The administration of intensive care units in an approved hospital for patients recovering from or awaiting open-heart surgery must be under the direction of a qualified physician approved by the cardiac surgeon.

2. A nursing supervisor must be permanently assigned to the intensive care units designated for cardiac surgery patients. The supervisor must have not less than 2 years of experience in intensive care nursing and not less than 1 year of current experience in intensive care nursing of patients recovering from open-heart surgery.

3. The nursing supervisor and the surgical team shall:

(a) Provide organized training and continuing in-service education to each nurse; and

(b) Determine that each nurse is qualified to perform services related to postcardiac surgery,

before assigning the nurse without direct supervision to full-time or periodic duty in the intensive care units.

4. One nurse on each shift must be designated as the nurse in charge for the intensive care units. There must be one nurse for not more than two cardiac surgery patients in the intensive care units for the first 24 hours after surgery.

(Added to NAC by Bd. of Health, eff. 8-31-89)

**NAC 449.61234 Intensive care facility: Equipment and supplies. ([NRS 449.0302](#))**

1. The following equipment must be immediately available to the intensive care facility:

- (a) A laryngoscope.
- (b) Endotracheal tubes.
- (c) Respirators.
- (d) Hypothermia equipment.
- (e) Tracheostomy sets.
- (f) Thoracotomy sets.
- (g) A board for massaging a closed chest.
- (h) An external pacemaker.
- (i) An external defibrillator.
- (j) Respiratory support equipment.
- (k) Intravenous drip counters.
- (l) An intravenous diffusion pump.

(m) Equipment which can remotely monitor, record and play back electrocardiographs and count extra systole pulses.

(n) An open-heart set with sternal spreader, staple remover, internal defibrillator [y] paddles, wire cutters and sufficient sutures and clamps.

(o) An intra-aortic balloon pump.

(p) An ambu bag.

2. There must be a supply of appropriate medicines stored within the intensive care facility.

3. Tele-transmitters and electronic rate counters must be used for patients with heart pacemakers while they are in the intensive care facility.

(Added to NAC by Bd. of Health, eff. 8-31-89)

**NAC 449.61236 Orientation and continuing education of personnel. ([NRS 449.0302](#))**

An approved hospital shall provide, under the direction of the cardiac surgeon, an orientation program and a program of continuing education for surgical nurses, technicians and any personnel who participate in the service for open-heart surgery.

(Added to NAC by Bd. of Health, eff. 8-31-89)

**NAC 449.61238 Maintenance of blood bank. ([NRS 449.0302](#))** An approved hospital shall maintain a blood bank which operates 24 hours a day under the direction of qualified specialists. These persons must be able to supply blood and blood derivatives to surgical teams assigned to open-heart surgery.

(Added to NAC by Bd. of Health, eff. 8-31-89)

**NAC 449.6124 Maintenance of cardiac catheterization laboratory. ([NRS 449.0302](#))**

1. An approved hospital shall maintain a cardiac catheterization laboratory which operates 24 hours a day under the direction of a qualified specialist.

2. The laboratory must be located in the hospital and must have sufficient equipment to perform:

- (a) Hemodynamic studies;
- (b) Preoperative elective studies;
- (c) Postoperative elective studies; and
- (d) Emergency procedures.

(Added to NAC by Bd. of Health, eff. 8-31-89)

*3. The hospital shall include information concerning the capacity, utilization, staffing and emergency availability of the cardiac catheterization laboratory in the annual report submitted to the Division pursuant to NAC 449.6125.*

*4. Each cardiac catheterization laboratory shall establish and maintain safety guidelines, practices and policies in accordance with NRS 459.010 to 459.290, inclusive, and regulations adopted pursuant thereto, to assure a safe environment for patients, visitors and personnel.*

*5. Each cardiac catheterization laboratory shall establish and follow electrical safety policies that include, without limitation:*

- (a) a safe primary electrical wiring system;*
- (b) electrical isolation of equipment attached to a patient;*
- (c) the use of an equipotential hardwired grounding system for all equipment; and*

*(d) periodic inspection of the electrical system and measurement of interequipment current leakage.*

*6. Each cardiac catheterization laboratory shall periodically inspect all equipment used by the laboratory and perform preventive maintenance at least as often as recommended by the manufacturer. The results of such inspection and preventive maintenance must be documented internally.*

***NAC 449.612405 Adult cardiac catheterization service standards (NRS 449.0302).*** *Applicable to each provider of adult cardiac catheterization services that performs procedures on patients who are 18 years of age or older.*

*1. Each provider of cardiac catheterization services shall:*

*(a) Designate in writing to the Division the level and scope of services it provides or intends to provide; and*

*(b) shall not represent, by signage, advertising or other promotional effort, that it provides a level of service for which it is not designated.*

*2. Each provider of cardiac catheterization services shall maintain a written protocol for the emergency transfer and care of patients who require emergency medical or surgical management during or immediately after cardiac catheterization.*

*3. Each provider of cardiac catheterization services Have access to the ancillary and support services necessary to meet the needs of the service, including immediate access to services for hematology and coagulation disorders, electrocardiography and diagnostic radiology, and reasonable access to additional support services required for patient care.*

*4. Each provider of cardiac catheterization services shall establish and maintain a quality assessment review process sufficient to review the appropriateness, technical quality, results and complications of cardiac catheterization procedures performed by each physician credentialed to perform such procedures.*

*5. Each provider of cardiac catheterization services establish written criteria specifying the number of procedures an appropriately privileged physician must perform to retain privileges to perform each procedure.*

*6. Each provider shall conduct an ongoing review, within 60 days after the procedure, of all cases involving mortality or significant morbidity.*

7. *Each provider shall establish and maintain a database or registry sufficient to support the review process required by this section and to document the results of analysis and review.*
8. *Adult cardiac catheterization services may be provided only in a permanent licensed hospital setting with inpatient medical and surgical services, intensive or critical care capability, post-procedure observation capability and adequate physician coverage to manage post-procedure complications.*

***NAC 449.612400. "Level I cardiac catheterization service" defined. (NRS 449.0302)*** *"Level I cardiac catheterization service" or "level I service" means an adult cardiac catheterization service located in a hospital without an on-site open-heart surgery service that provides only diagnostic cardiac catheterization procedures on an organized regular basis.*

1. *Each Level I service will perform only diagnostic cardiac catheterization procedures to diagnose anatomical and/or physiological problems in the heart. Diagnostic procedures include:*
  - (a) Intracoronary administration of drugs*
  - (b) Left heart catheterization*
  - (c) Right heart catheterization*
  - (d) Coronary angiography*
  - (e) Basic diagnostic electrophysiology studies not involving transseptal puncture*
  - (f) Intra-aortic balloon pump or, if required for patient stabilization for transfer, placement of percutaneous left ventricular assist device*
  - (g) Device implantation, including, but not limited to, defibrillators*
2. *Each Level I service will implement patient exclusion criteria.*
3. *Each Level I service will comply with the personnel and staffing requirements set forth in Nevada regulations, including NAC Chapter 449, governing surgical privileges, cardiovascular qualifications, and Nevada State Board of Nursing scope of practice rules.*
4. *Each Level I service will comply with the facilities, equipment, and supplies requirements set forth in the Nevada Administrative Code for medical facilities, as overseen by the state's Nevada Health Authority.*
5. *Each Level I service will comply with the safety standards set forth by the state's Board of Health governing patient rights, adverse event reporting, and infection control.*

6. *Each Level I service will maintain a formal written transfer protocol for emergency medical/surgical management with a licensed hospital that provides open-heart surgery services (receiving service), which can be reached expeditiously by available emergency vehicle within a reasonable amount of time and that provides the greatest assurance for patient safety. Each protocol must include:*
  - *Explicit procedures for emergency transfer coordination.*
  - *Criteria for designating the receiving facility.*
  - *Pre-established arrangements with local Emergency Medical Services.*

*NAC 449.612401. "Level II cardiac catheterization service" means an adult cardiac catheterization service located in a hospital without an on-site open-heart surgery service that provides diagnostic and authorized therapeutic cardiac catheterization procedures on an organized and regular basis.*

1. *A Level II cardiac catheterization service may perform only diagnostic procedures and those therapeutic procedures authorized by the Division.*
2. *A Level II cardiac catheterization service shall not perform any procedure prohibited by the Division, including, without limitation, procedures designated by the Division as requiring on-site open-heart surgical backup or a higher level of service.*
3. *Except as otherwise authorized by the Division, a hospital must have provided at least 1 year of diagnostic cardiac catheterization service before it may obtain approval to provide a Level II cardiac catheterization service. The Division may grant accelerated designation on a case-by-case basis if the hospital demonstrates that patient safety and service readiness will be maintained.*
4. *Each Level II cardiac catheterization service shall implement written patient-screening and case-selection criteria approved by the medical director and consistent with standards adopted by the Division.*
5. *Each Level II cardiac catheterization service shall maintain personnel, equipment and supplies sufficient to perform authorized procedures safely, including personnel capable of airway management, endotracheal intubation and ventilator management within the scope of their licensure or certification, both on-site and during transfer of a patient if necessary.*
6. *Each Level II cardiac catheterization service shall comply with the safety, staffing, facility and equipment standards prescribed by the Division.*

7. Each Level II cardiac catheterization service shall comply with the radiation safety, electrical safety and equipment maintenance requirements set forth in NAC 449.6124.

8. Each Level II cardiac catheterization service shall comply with NAC 449.612405.

**NAC 449.612402.** Each Level II cardiac catheterization service shall maintain a formal written transfer protocol for emergency medical or surgical management with a licensed hospital that provides open-heart surgery services and that can be reached expeditiously by available emergency vehicle within a reasonable time.

2. The transfer protocol required by subsection 1 must include, without limitation:

(a) indications, contraindications and other criteria for emergency transfer;

(b) assurance of timely initiation of appropriate medical or surgical management;

(c) assurance that surgical backup is available for urgent cases during all hours of operation;

(d) mechanisms for continued substantive communication between the services that are parties to the agreement and between their medical directors and physicians;

(e) provisions for collaborative training among staff of the services that are parties to the agreement;

(f) provisions for recommendations by the medical director of the receiving service regarding credentialing criteria; and

(g) provisions for annual drills to review and test the transfer protocol, except that an actual emergent patient transfer consistent with the protocol within the calendar year satisfies the requirement for an annual drill.

3. Each Level II cardiac catheterization service shall maintain a written agreement with a ground or air ambulance service that can commit to timely availability and is capable of advanced cardiac life support and intra-aortic balloon pump transfer of a patient to the receiving hospital.

4. Major complications and emergency transfers must be reviewed at least once every 60 days through the hospital's quality assessment process.

5. Each Level II cardiac catheterization service shall enroll and participate in a data registry approved by the Division to monitor operator and institutional volumes and outcomes.

6. Each Level II cardiac catheterization service shall submit an annual report to the Division, in a form prescribed by the Division, that maintains patient confidentiality and includes

*procedure volumes, therapeutic interventions, post-procedure in-hospital mortality, vascular access injury requiring intervention, major bleeding, emergency transfers and emergency procedures performed outside the ordinary scope of the service.*

- 7. Before the performance of any procedure, each Level II cardiac catheterization service shall obtain a signed informed consent form acknowledging that the procedure is being performed in a cardiac catheterization service without an on-site open-heart surgery service and that, if necessary as the result of an adverse event, the patient may be transferred to a receiving service for medical or surgical management.*
- 8. Nothing in this section prohibits the provision of emergency care when clinically indicated. If action outside the authorized scope of a Level II cardiac catheterization service is required because of an emergency, the hospital shall notify the Division within 48 hours in a manner that maintains patient confidentiality and indicates when the incident occurred, the nature of the emergency, the actions taken and the outcome.*

*NAC 449.612403. "Level III cardiac catheterization service" means an adult cardiac catheterization service located in a hospital with an on-site open-heart surgery service that provides all levels of diagnostic and therapeutic cardiac catheterization procedures authorized by the Division.*

- 1. Each Level III cardiac catheterization service shall operate on an organized and regular 24-hour-a-day, 7-day-a-week basis to perform primary percutaneous coronary intervention.*
- 2. Except as otherwise authorized by the Division, a hospital must have provided at least 1 year of diagnostic cardiac catheterization service before it may obtain approval to provide a Level III cardiac catheterization service. The Division may grant accelerated designation on a case-by-case basis if the hospital demonstrates that patient safety and service readiness will be maintained.*
- 3. Each Level III cardiac catheterization service must have:*
  - (a) an on-site adult open-heart surgery service available within the same hospital as the cardiac catheterization laboratory and immediately accessible from the cardiac catheterization laboratory by gurney;*
  - (b) an experienced cardiovascular surgical team that is readily available in less than 60 minutes on a 24-hour-a-day basis if emergency open-heart surgery is required; and*

*(c) support services sufficient to provide comprehensive diagnostic and therapeutic cardiac catheterization services safely.*

- 4. Each Level III cardiac catheterization service shall comply with the personnel, staffing, facility, equipment and safety standards prescribed by the Division.*
- 5. Major complications and emergency transfers must be reviewed at least once every 60 days through the hospital's quality assessment process.*
- 6. Each Level III cardiac catheterization service shall enroll and participate in a data registry approved by the Division to monitor operator and institutional volumes, outcomes and procedural appropriateness.*
- 7. Each Level III cardiac catheterization service shall submit an annual report to the Division, in a form prescribed by the Division, that maintains patient confidentiality and includes procedure volumes, interventional procedures, post-procedure in-hospital mortality, vascular access injury requiring intervention and major bleeding.*
- 8. Before the performance of any procedure, each Level III cardiac catheterization service shall obtain a signed informed consent form in accordance with hospital policy and applicable law.*
- 9. Each Level III cardiac catheterization service shall comply with the radiation safety, electrical safety and equipment maintenance requirements set forth in NAC 449.6124.*
- 10. Each Level III cardiac catheterization service shall comply with NAC 449.612405.*

**NAC 449.61242 Maintenance of medical laboratory.** ([NRS 449.0302](#)) An approved hospital shall maintain a medical laboratory which operates 24 hours a day. The laboratory must have sufficient equipment to:

1. Perform standard laboratory tests;
2. Make pH determinations; and
3. Analyze samples for blood-gas and electrolytes.

(Added to NAC by Bd. of Health, eff. 8-31-89)

**NAC 449.61244 Maintenance of facilities to perform contrast studies and equipment to review films of operations.** ([NRS 449.0302](#)) An approved hospital shall maintain:

1. Facilities in which contrast studies of the cardiovascular system may be performed.
2. Film projectors and a proper filing system so that surgeons may review films of cardiac catheterization operations at any time.

(Added to NAC by Bd. of Health, eff. 8-31-89)

**NAC 449.61246 Maintenance of registry to record results for each patient.** ([NRS 449.0302](#)) 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. The patient's patient identification number.
2. The patient's race.
3. The patient's age.
4. The patient's sex.
5. Any history of hypertension, smoking, diabetes mellitus, cerebrovascular disease, coronary bypass, myocardial infarction, 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. The patient's ASA acuity classification.
10. The patient's 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 the patient is an elective, emergency or transfer case.
14. The number of days he or she is intubated.
15. The number of days he or she is in the cardiac surgery unit.
16. The length of the patient's hospital stay.
17. The location to which he or she is discharged.
18. A record of his or her 30-day follow-up examination.
19. A record of his or her 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.

(Added to NAC by Bd. of Health, eff. 8-31-89)

**NAC 449.61248 Maintenance of program to follow recovery of patient. (NRS 449.0302)**

An approved hospital shall maintain a comprehensive program for following the recovery and progress of the patient toward his or her optimum condition of health. The condition of the patient must be assessed after discharge from the hospital by the surgeon or his or her designee.

(Added to NAC by Bd. of Health, eff. 8-31-89)

**NAC 449.6125 Annual review ~~[and inspection]~~ of reports and data registries; triennial on-site inspection of hospital.**

Unless the hospital has notified the Division that it has ceased to perform open-heart surgeries:

~~[a surveyor of health facilities from the Division shall review each approved hospital annually to verify that the hospital is complying with the provisions of NAC 449.612 to 449.61256, inclusive.]~~

*1. The Division shall conduct an annual review of reports and data registries offsite for each approved hospital to verify compliance with the provisions of NAC 449.612 to 449.61256, inclusive.*

*2. The annual report required by subsection 1 must include, without limitation:*

*(a) Procedure volumes for open-heart surgery;*

*(b) Performance measures and quality indicators designated by the Division;*

*(c) Information concerning risk-adjusted mortality, morbidity and other outcomes required by the Division; and*

*(d) Information concerning the hospital's cardiac catheterization laboratory and related cardiac catheterization services, including, without limitation, capacity, utilization, staffing and emergency availability, to the extent required by the Division.*

*3. The Division shall conduct a mandatory physical on-site inspection of each approved hospital, including, without limitation, review of the hospital's service for open-heart surgery and related cardiac catheterization services, at least once every 3 years.*

*4. The Division may conduct an unscheduled on-site inspection at an interval less than 3 years if an offsite review, data metric anomaly, or excessive mortality rate triggers a need for further evaluation under NAC 449.61254.*

**NAC 449.61252 ~~[Annual inspection]~~ Annual offsite review of hospital: Assessment of reports, registries, and rate of mortality. (NRS 449.0302)**

~~[1.—As a part of the annual inspection of each approved hospital, the Division shall perform a detailed review of the patient files relating to all mortalities at the hospital.]~~

1. The Division's ~~[annual inspection]~~ *annual offsite review* of an approved hospital must include a detailed review of the patient files relating to all mortalities at the hospital *and the performance measures, quality indicators, and surgical data submitted under subsection 2 of NAC 449.6125.*
2. In assessing whether a hospital's adjusted rate of mortality 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)

#### ***NAC 449.61253 Guidelines for Surgical Staff and Program Performance Review***

1. *Each approved hospital shall adopt written policies for the internal review of surgeon-specific and program-specific performance using risk-adjusted clinical outcomes.*
2. *The written policies required by subsection 1 must provide for review when:*
  - (a) *a surgeon's risk-adjusted mortality or major morbidity is materially worse than expected;*
  - (b) *a surgeon's case volume or a program's case volume is sufficiently low to raise a concern regarding maintenance of competency; or*
  - (c) *a trend in complications suggests a material threat to patient safety.*
3. *The hospital shall document all internal reviews and any corrective measures taken, including, without limitation, mentoring, proctoring, changes in case selection, temporary limitations on privileges or other actions reasonably calculated to improve patient safety and quality.*
4. *Upon request of the Division, the hospital shall make available documentation demonstrating compliance with this section, except that peer review records remain subject to any privilege or confidentiality provided by law.*

**NAC 449.61254 Further review or *unscheduled* on-site inspection for failure to comply with provisions or for excessive rate of mortality; notice; plan for compliance. ([NRS 449.0302](#))**

1. If the *annual offsite* review [~~conducted~~] *as determined* 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, or if a facility's adjusted rate of mortality, after considering the factors enumerated in [NAC 449.61252](#), is considered excessive, the Division may, at the expense of the hospital, require:

(a) A second *offsite* review; or

(b) An *unscheduled physical* on-site inspection, conducted by one or more of the persons specified in [NAC 449.61208](#). When the 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 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 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 made by the person or persons who conducted the review or inspection pursuant to subsection 1.

3. If the 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 Division has received the plan. After that time, the Division may require another review of the hospital pursuant to [NAC 449.6125](#) or a review or inspection conducted pursuant to subsection 1 of this section.

(Added to NAC by Bd. of Health, eff. 8-31-89; A by R107-98, 3-18-99)

*"4. If the Division receives notice pursuant to subsection 4 of NAC 449.61212 or otherwise determines that an approved hospital has experienced a gap in the specialty coverage required by subsection 6 of NAC 449.61218, the Division may immediately require a focused review or on-site inspection of the hospital. The hospital shall submit any corrective action plan required by the Division within the time prescribed by the Division. During any period in which elective open-heart surgery is suspended pursuant to subsection 4 of NAC 449.61212, the hospital shall not resume elective open-heart surgery until the Division has verified restoration of continuous coverage and determined that the hospital has satisfied any corrective actions required pursuant to this section."*

**NAC 449.61256 Denial, suspension or revocation of approval: Grounds; hearing. ([NRS 449.0302](#))**

1. The Division may deny, suspend or revoke its approval because of the failure of the hospital affected to comply with any provision of [NAC 449.612](#) to [449.61256](#), inclusive.

2. The Division shall advise the hospital affected in writing whenever it intends:

(a) To deny an application for approval or for renewal of approval;

(b) To revoke approval; or

(c) To order a hospital to cease and desist providing services for open-heart surgery.

3. The hospital affected may request a hearing on the proposed action of the Division. The hearing must be conducted in accordance with the procedures set forth in [NAC 439.300](#) to [439.395](#), inclusive.

(Added to NAC by Bd. of Health, eff. 8-31-89; A by R044-97, 10-30-97)