PROPOSED REGULATION OF THE

STATE BOARD OF HEALTH

LCB File No. R141-26

September 10, 2026

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

AUTHORITY: §§ 1-15 and 42, NRS 449.0302; §§ 16-41, NRS 449.0302 and 449.087.

A REGULATION relating to health care; requiring a hospital that provides cardiac catheterization services to be approved by the Health Care Purchasing and Compliance Division of the Nevada Health Authority; prescribing requirements governing such hospitals; requiring a hospital that is approved to conduct open-heart surgery to adopt policies for certain reviews; requiring a hospital to suspend the performance of open-heart surgery in certain circumstances; revising the terminology used to refer to such a hospital; clarifying the applicability of provisions relating to open-heart surgery; revising certain requirements governing the operation and oversight of hospitals that perform open-heart surgery; authorizing the Division to take certain disciplinary action against a cardiac catheterization service under certain circumstances; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law requires the State Board of Health to adopt regulations governing the licensing of hospitals. (NRS 449.0302) Existing law also requires a licensee to obtain the approval of the Health Care Purchasing and Compliance Division of the Nevada Health Authority before performing open-heart surgery. (NRS 449.087) **Sections 2-15 and 42** of this regulation establish a regulatory scheme for hospitals performing adult cardiac catheterization services. **Section 8** requires a hospital to submit an application to the Division for approval to: (1) perform adult cardiac catheterization services; or (2) change the level of adult cardiac catheterization services that the hospital performs. **Sections 3-5** define "level I cardiac catheterization service," "level II cardiac catheterization service" and "level III cardiac catheterization service," respectively. **Section 9**: (1) sets forth certain general duties that apply to all adult cardiac catheterization services; and (2) prohibits a hospital from performing or representing that it performs cardiac catheterization procedures that the hospital is not approved to perform.

Section 10 authorizes a level I cardiac catheterization service to perform only diagnostic cardiac catheterization procedures, and **section 2** defines the term "diagnostic cardiac catheterization procedures." **Section 10** also requires a level I cardiac catheterization service to implement criteria to ensure that a level I cardiac catheterization service is appropriate for the patient. **Section 12** authorizes a level II cardiac catheterization service to perform only diagnostic

cardiac catheterization procedures and certain therapeutic cardiac catheterization procedures. **Section 12** also prescribes various duties of a level II cardiac catheterization service. **Sections 11 and 13** require a level I cardiac catheterization service or level II cardiac catheterization service, respectively, to enter into an agreement with a receiving service to provide for the transfer of patients to the receiving service in an emergency. **Section 7** defines the term "receiving service" to mean a hospital that is approved to perform open-heart surgery and has entered into such an agreement. **Section 13** additionally requires a level II cardiac catheterization service to enter into an agreement with a local provider of emergency medical services to transport patients to the receiving service. **Section 6** defines "provider of emergency medical services" to mean a person or entity that holds a permit to operate an ambulance, air ambulance or vehicle of a fire-fighting agency.

Section 14 prescribes requirements for and duties of a level III cardiac catheterization service. **Section 15** requires a level II or level III cardiac catheterization service to annually report certain information to the Division. **Section 18** of this regulation establishes the applicability of the definitions set forth in **sections 2-7**.

Existing regulations define "approved hospital" to mean a hospital that has obtained approval from the Division to perform open-heart surgery. (NAC 449.612012) **Sections 19 and 24-40** of this regulation revise that term to "approved open-heart surgery hospital" to clearly differentiate such hospitals from hospitals that are approved to perform cardiac catheterization procedures.

Sections 20 and 21 of this regulation revise the definitions of the terms "cardiac surgery" and "open-heart surgery" to clarify that provisions relating to open-heart surgery apply to procedures involving the use of a heart-lung bypass machine directly or in standby fashion.

Section 16 of this regulation requires an approved open-heart surgery hospital to adopt written policies for the internal review of the performance of each surgeon and procedure. **Section 17** of this regulation provides for the automatic suspension of the authority of a hospital to perform open-heart surgery if the hospital does not have the coverage by providers of health care required by existing regulations. (NAC 449.61218-449.61224)

Existing regulations require a hospital to be inspected by a site inspection team before the hospital may be approved to perform open-heart surgery. (NAC 449.61208) **Section 23** of this regulation requires the inspection team to make certain findings after an inspection, in addition to the findings required by existing regulations. (NAC 449.61208)

Existing regulations require an approved open-heart surgery hospital to perform such surgeries at certain rates. (NAC 449.61214) **Section 24**: (1) prohibits the Division from denying, suspending or revoking the approval of a hospital to perform open-heart surgery because the hospital is not performing such surgeries at the specified rates if the hospital meets certain requirements indicating the continued safety of open-heart surgery at the hospital; and (2) requires the Division to consider certain information that relates to the volume of open-heart surgeries and the quality of care at the hospital when determining whether the hospital meets those requirements. **Sections 22 and 23** of this regulation make conforming changes to reflect that **section 24** is removing the requirement that an approved open-heart surgery hospital must perform such surgeries at the specified rates under all circumstances.

Existing regulations require the primary surgeon on a surgical team assigned to an open-heart surgery to be certified by the American Board of Thoracic Surgery or eligible for such certification. (NAC 449.61218) **Section 25** removes authorization for a surgeon who is eligible

for such certification but is not certified to serve as a primary surgeon, thereby requiring a primary surgeon to actually hold such certification.

Existing regulations require an approved open-heart surgery hospital to maintain a cardiac catheterization laboratory. (NAC 449.6124) **Section 34** additionally requires a hospital that hosts a level II or level III cardiac catheterization service to maintain a cardiac catheterization laboratory. **Section 34** also requires: (1) such a laboratory to establish and follow policies for electrical safety; and (2) the employees of such a laboratory to regularly inspect the equipment in such a laboratory.

Existing regulations require the Division to annually review each approved open-heart surgery hospital to verify compliance with applicable regulations. (NAC 449.6125) **Sections 39 and 40** require: (1) an approved open-heart surgery hospital to submit an annual report to the Division; (2) the Division to conduct an annual off-site review of certain reports and data of each approved open-heart surgery hospital; and (3) the Division to conduct a triennial on-site inspection of each approved open-heart surgery hospital. **Section 41** of this regulation authorizes the Division to conduct a second off-site review or unscheduled on-site inspection if the Division determines that: (1) the hospital is not in full compliance with the all regulatory requirements; (2) there is an anomaly in the hospital's data; or (3) the adjusted rate of mortality of open-heart surgery at the hospital is excessive. **Section 17** authorizes the Division to conduct a similar review if an approved open-heart surgery has experienced a lapse in coverage of required providers of health care.

Section 42 authorizes the Division to discipline a hospital that is approved to perform cardiac catheterization procedures if the hospital fails to comply with the provisions of **sections 2-17** and certain existing regulations. (NRS 449.612-449.61256)

Section 1. Chapter 449 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 17, inclusive, of this regulation.

Sec. 2. ***"Diagnostic cardiac catheterization procedures" means procedures to diagnose anatomical or physiological problems in the heart. The term includes, without limitation:***

1. The intracoronary administration of drugs;

2. Left heart catheterization;

3. Right heart catheterization;

4. Coronary angiography;

5. Basic diagnostic electrophysiology studies not involving transseptal puncture;

6. An intra-aortic balloon pump or, if required to stabilize a patient for transfer, placement of a percutaneous left ventricular assist device; and

7. The implantation of a device, including, without limitation, a defibrillator.

Sec. 3. *"Level I cardiac catheterization service" means an adult cardiac catheterization service that:*

1. Is located in a hospital that is not an approved open-heart surgery hospital; and

2. Performs only diagnostic cardiac catheterization procedures on an organized, regular basis.

Sec. 4. *"Level II cardiac catheterization service" means an adult cardiac catheterization service that:*

1. Is located in a hospital that is not an approved open-heart surgery hospital; and

2. Performs only diagnostic cardiac catheterization procedures and therapeutic cardiac catheterization procedures authorized by section 12 of this regulation on an organized, regular basis.

Sec. 5. *"Level III cardiac catheterization service" means an adult cardiac catheterization service that:*

1. Is located in an approved open-heart surgery hospital; and

2. Performs all levels of diagnostic cardiac catheterization procedures and therapeutic cardiac catheterization procedures.

Sec. 6. *"Provider of emergency medical services" means a service that holds a permit issued pursuant to NRS 450B.200.*

Sec. 7. *"Receiving service" means an approved open-heart surgery hospital that has entered into an agreement with a level I cardiac catheterization service or a level II cardiac catheterization service pursuant to section 11 or 13, as applicable, of this regulation.*

Sec. 8. *1. A hospital that desires to newly perform adult cardiac catheterization procedures or change the level of adult cardiac catheterization services that the hospital performs must submit an application to the Division, on a form prescribed by the Division, for approval.*

2. To qualify for approval pursuant to subsection 1, a hospital must:

(a) Hold a license that is not provisional;

(b) Perform medical and surgical services in an inpatient setting;

(c) Have the capability to provide intensive or critical care and post-procedure observation and care; and

(d) Have sufficient staffing by physicians to manage any post-procedure complications.

3. Except as otherwise authorized by subsection 4, before the Division approves a level II cardiac catheterization service or level III cardiac catheterization service, the applicant must have provided diagnostic cardiac catheterization procedures as an approved cardiac catheterization service for at least 1 year.

4. The Division may approve a level II cardiac catheterization service or level III cardiac catheterization service that does not meet the requirements of subsection 3 if the Division determines that the applicant will be able to maintain the safety of patients if the hospital is approved as a level II cardiac catheterization service or level III cardiac catheterization service, as applicable.

5. The Division may inspect an applicant to ensure compliance with NAC 449.612 to 449.61256, inclusive, and sections 2 to 17, inclusive, of this regulation.

6. The Division may approve an application submitted pursuant to subsection 1 if the Division determines the applicant meets the requirements set forth in NAC 449.612 to

449.61256, inclusive, and sections 2 to 17, inclusive, of this regulation to provide the level of cardiac catheterization service for which the hospital is seeking approval.

Sec. 9. *1. An adult cardiac catheterization service shall:*

(a) Ensure access to ancillary and support services necessary to meet the needs of each patient, including, without limitation, immediate access to services for hematology and coagulation disorders, electrocardiography and diagnostic radiology.

(b) Establish and maintain a process to review the quality of cardiac catheterization procedures that is sufficient to review the:

(1) Appropriateness of each procedure;

(2) Technical quality of each procedure; and

(3) Results and complications of the cardiac catheterization procedures performed by each physician.

(c) Establish written criteria specifying the number of cardiac catheterization procedures a privileged physician must perform to retain privileges to perform cardiac catheterization procedures.

(d) Not later than 60 days after a cardiac catheterization procedure that resulted in mortality or significant morbidity, conduct a review of the case.

(e) Establish and maintain a database or registry sufficient to support the review process required by paragraphs (b) and (d) and to document the results of each review.

2. A hospital shall not:

(a) Perform a cardiac catheterization procedure that the hospital is not approved to perform pursuant to section 8 of this regulation; or

(b) Represent, by signage, advertising or other promotional effort, that the hospital performs a cardiac catheterization procedure described in paragraph (a).

Sec. 10. *A level I cardiac catheterization service:*

1. May perform only diagnostic cardiac catheterization procedures; and

2. Shall implement criteria to screen patients and cases to ensure that a level I cardiac catheterization service will provide the appropriate level of care for each patient. Such criteria must be:

(a) Approved by the medical director of the hospital in which the level I cardiac catheterization service is located; and

(b) Consistent with national standards and clinical guidelines governing cardiac catheterization.

Sec. 11. *1. A level I cardiac catheterization service shall enter into an agreement with a receiving service. The agreement must establish a formal, written protocol for transferring patients to the receiving service when necessary to manage a medical or surgical emergency.*

2. A receiving service that is a party to an agreement entered into pursuant to subsection 1 must be located sufficiently near the hospital where the level I cardiac catheterization service is located that an emergency vehicle is able to leave the hospital and reach the receiving service within a reasonable amount of time to ensure, to the greatest extent possible, the safety of any patient who requires transfer.

3. A protocol for transferring patients included in an agreement entered into pursuant to subsection 1 must include, without limitation:

(a) Clear and specific procedures for coordinating the emergency transfer of patients;

(b) Criteria for designating the receiving service; and

(c) Arrangements with a local provider of emergency medical services to transfer a patient from the level I cardiac catheterization service to the receiving service.

Sec. 12. *1. A level II cardiac catheterization service may only perform:*

(a) Diagnostic cardiac catheterization procedures; and

(b) Therapeutic cardiac catheterization procedures authorized for a level II cardiac catheterization service by applicable federal regulations and national clinical guidelines for level II cardiac catheterization services.

2. A level II cardiac catheterization service shall:

(a) Implement criteria to ensure that a level II cardiac catheterization service will provide the appropriate level of care for the patient. Such criteria must be:

(1) Approved by the medical director of the hospital in which the level II cardiac catheterization service is located; and

(2) Consistent with national standards and clinical guidelines governing the screening of cardiac catheterization patients and cases.

(b) Maintain personnel, equipment and supplies sufficient to safely perform the procedures described in subsection 1. Such personnel must include, without limitation, personnel capable of performing airway management, endotracheal intubation and ventilator management, both on-site and during the transfer of a patient.

(c) Comply with the personnel, staffing, facility, equipment and safety standards prescribed by the applicable federal regulations and nationally recognized standards for a level II cardiac catheterization service.

(d) Review each major complication or emergency transfer not later than 60 days after the occurrence of the complication or transfer.

(e) Maintain a data registry to monitor operator and institutional volumes and outcomes.

(f) Before the performance of any cardiac catheterization procedure, obtain the informed consent of the patient on a signed and dated form on which the patient acknowledges that:

(1) The procedure is being performed in a hospital without an on-site unit for open-heart surgery; and

(2) If necessary due to an adverse event, the patient may be transferred to a receiving service.

3. A level II cardiac catheterization service shall not perform any cardiac catheterization procedure if nationally recognized standards and clinical guidelines require the procedure to be performed in a hospital that performs open-heart surgery.

4. Nothing in NAC 449.612 to 449.61256, inclusive, and sections 2 to 17, inclusive, of this regulation prohibits a level II cardiac catheterization service from providing emergency care when such care is clinically indicated. If action outside the authorized scope of a level II cardiac catheterization service as described in this section is required because of an emergency, the level II cardiac catheterization service shall, in a manner that maintains patient confidentiality, notify the Division not later than 48 hours after taking such action. Such notification must include:

(a) The time and date on which the incident occurred; and

(b) A description of the nature of the emergency, the actions taken in response to the emergency and the outcome of those actions.

Sec. 13. *1. A level II cardiac catheterization service shall enter into an agreement with a receiving service. The agreement must:*

(a) Establish a formal, written protocol for transferring patients to the receiving service when necessary to manage a medical or surgical emergency; and

(b) Additionally include, without limitation:

(1) Provisions for collaborative training between the staff of the level II cardiac catheterization service and the staff of the receiving service; and

(2) Procedures for the medical director of the receiving service to make recommendations concerning the criteria of the level II cardiac catheterization service for credentialing physicians.

2. A receiving service that is a party to an agreement entered into pursuant to subsection 1 must be located sufficiently near the hospital where the level II cardiac catheterization service is located that an emergency vehicle is able to leave the hospital and reach the receiving service within a reasonable amount of time to ensure, to the greatest extent possible, the safety of any patient who requires transfer.

3. A protocol for transferring patients included in an agreement entered into pursuant to subsection 1 must include, without limitation:

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

(b) Assurances from the receiving service:

(1) That the receiving service will, in a timely manner, initiate appropriate medical or surgical management of each patient who is transferred under the protocol; and

(2) That surgical teams are available to attend to urgent cases transferred to the receiving service during all hours of operation;

(c) Mechanisms for continued substantive communication between the level II cardiac catheterization service and the receiving service, and the medical directors and physicians of those services; and

(d) Provisions for annual drills to review and test the transfer protocol, except that an actual emergent patient transfer conducted consistently with the protocol satisfies the requirement to conduct an annual drill during the calendar year in which the emergent transfer occurs.

4. A level II cardiac catheterization service shall enter into a written agreement with a local provider of emergency medical services to provide transportation from the hospital where the level II cardiac catheterization service is located to the receiving service with which the level II cardiac catheterization service has entered into an agreement pursuant to subsection 1. The provider of emergency medical services must:

(a) Be capable of:

(1) Providing advanced cardiac life support; and

(2) Transferring a patient who is dependent upon an intra-aortic balloon pump to the receiving service; and

(b) Commit to being available at all times to provide the services described in paragraph (a) in a timely manner.

Sec. 14. *1. A level III cardiac catheterization service must be:*

(a) Able to perform primary percutaneous coronary interventions 24 hours each day, 7 days each week; and

(b) Located within an approved open-heart surgery hospital, with open-heart surgery immediately accessible by gurney from the cardiac catheterization laboratory maintained pursuant to NAC 449.6124.

2. A level III cardiac catheterization service shall:

(a) Maintain support services sufficient to safely provide comprehensive diagnostic and therapeutic cardiac catheterization services.

(b) Ensure that a cardiovascular surgical team is available to reach the level III cardiac catheterization service in less than 60 minutes at all times, 24 hours each day.

(c) Comply with the personnel, staffing, facility, equipment and safety standards prescribed by the applicable federal regulations and nationally recognized standards for a level III cardiac catheterization service.

(d) Review each major complication or emergency transfer not later than 60 days after the complication or transfer in accordance with a quality assessment process established by the hospital where the level III cardiac catheterization service is located.

(e) Maintain a data registry to monitor surgeon and institutional volumes and outcomes and the appropriateness of procedures.

(f) Before the performance of any procedure, obtain the informed consent of the patient in accordance with a policy established by the level III cardiac catheterization service.

Sec. 15. *A level II cardiac catheterization service or level III cardiac catheterization service shall annually submit to the Division, in a manner that maintains patient confidentiality and on a form prescribed by the Division, a report that includes, without limitation, information concerning:*

1. The volume of each cardiac catheterization procedure performed by the service during the immediately preceding year;

2. The cardiac catheterization procedures performed by the service for therapeutic or interventional purposes during the immediately preceding year;

3. Mortality following a cardiac catheterization procedure that occurred in the hospital during the immediately preceding year;

4. Injuries to patients which resulted from vascular access and required intervention during the immediately preceding year;

5. Incidents of major bleeding by a patient as a result of a cardiac catheterization procedure during the immediately preceding year; and

6. For a level II cardiac catheterization service:

(a) Emergency transfers made to a receiving service during the immediately preceding year under the agreement entered into pursuant to section 13 of this regulation; and

(b) The rendering of emergency care outside the authorized scope of a level II cardiac catheterization service pursuant to subsection 4 of section 12 of this regulation during the immediately preceding year.

Sec. 16. *1. Each approved open-heart surgery hospital shall adopt written policies for the internal review of the performance of each surgeon and procedure using risk-adjusted clinical outcomes.*

2. The written policies required by subsection 1 must provide for review when:

(a) The risk-adjusted mortality or major morbidity rates of open-heart surgery procedures performed by a surgeon are materially worse than those of similarly situated surgeons;

(b) The volume of cases, either in total or per specific procedure, of a surgeon or the approved open-heart surgery hospital raises a concern about the ability of the surgeon or hospital to maintain competence; or

(c) A trend in complications suggests a material threat to the safety of patients.

3. An approved open-heart surgery hospital shall document all internal reviews and any corrective measures taken as a result of such reviews, including, without limitation, mentoring, proctoring, changes in the selection of cases, temporary limitations on privileges or other actions reasonably calculated to improve the safety of patients and quality of care.

4. Upon the request of the Division, the approved open-heart surgery hospital shall make available documentation demonstrating compliance with this section.

Sec. 17. *1. An approved open-heart surgery hospital shall immediately notify the Division if, for more than 48 continuous hours or 10 cumulative days in a calendar year, the hospital does not have coverage by the providers of health care described in NAC 449.61218 to 449.61224, inclusive.*

2. Upon notifying the Division pursuant to subsection 1, or if the Division otherwise determines that an approved open-heart surgery hospital has experienced a lapse in coverage described in subsection 1:

(a) The authority of the hospital to perform elective open-heart surgery is suspended; and

(b) The Division may immediately require an off-site review or an on-site inspection of the hospital. Such a review or inspection must follow the procedures established in NAC 449.61254.

3. The suspension described in paragraph (a) of subsection 2 is effective on the day on which:

(a) The approved open-heart surgery hospital notifies the Division of the lapse of coverage pursuant to subsection 1; or

(b) The Division notifies the approved open-heart surgery hospital that the Division has determined that there was a lapse in coverage described in subsection 1.

4. The Division may require an approved open-heart surgery hospital to submit, within a time prescribed by the Division, a corrective action plan to ensure that continuous coverage by providers of health care described in NAC 449.61218 to 449.61224, inclusive, is restored and maintained.

5. An approved open-heart surgery hospital shall not resume elective open-heart surgery until the Division has verified the restoration of continuous coverage by providers of health care described in NAC 449.61218 to 449.61224, inclusive, and has determined that the hospital has performed any corrective actions required pursuant to subsection 4. During the period of suspension, the hospital may provide only emergency stabilization and any emergency procedures expressly authorized by the Division.

6. An approved open-heart surgery hospital shall maintain written evidence, which the Division may verify, demonstrating that the hospital maintains on-call coverage at all times by the providers of health care described in NAC 449.61218 to 449.61224, inclusive.

Sec. 18. 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 17, inclusive, of this regulation*** unless the context otherwise requires, the words and terms defined in NAC 449.612011 to 449.612017, inclusive, ***and sections 2 to 7, inclusive, of this regulation*** have the meanings ascribed to them in those sections.

Sec. 19. NAC 449.612012 is hereby amended to read as follows:

449.612012 "Approved ***open-heart surgery*** hospital" means a hospital that has obtained approval from the Division to perform open-heart surgery.

Sec. 20. NAC 449.612014 is hereby amended to read as follows:

449.612014 "Cardiac surgery" means an operation performed on the heart or on the blood vessels connected to the heart ***or a replacement of the heart valves*** in which access to the area of interest is provided by means of an incision in the wall of the thorax or ***minimally invasive access*** for which the use of a heart-lung bypass machine ~~[is required.]~~ ***may be used directly or in a standby fashion.***

Sec. 21. NAC 449.612017 is hereby amended to read as follows:

449.612017 "Open-heart surgery" means any cardiac surgery requiring the use of a heart-lung bypass machine ~~[.]~~ ***directly or in a standby fashion.***

Sec. 22. 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 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 ~~[.]~~ ***, and sections 2 to 17, 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]~~ ***set forth in subsection 1 of*** 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]~~ ***set forth in subsection 1 of*** 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.

Sec. 23. NAC 449.61208 is hereby amended to read as follows:

449.61208 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 ~~[.]~~ ***, and sections 2 to 17, 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]~~ ***set forth in subsection 1 of*** NAC 449.61214.

(f) The systems of the hospital to assess quality and improve performance.

(g) Whether the hospital is enrolled and participates in a nationally recognized clinical outcomes registry for adult cardiac surgery as described in paragraph (a) of subsection 2 of NAC 449.61214.

(h) The capacity of the hospital to provide emergency surgery and postoperative intensive care on a continuous basis.

(i) The extent to which the service is necessary to preserve reasonable geographic access to open-heart surgery within the region from which the hospital receives referrals.

Sec. 24. NAC 449.61214 is hereby amended to read as follows:

449.61214 ~~[After]~~ ***1. An approved open-heart surgery hospital shall maintain sufficient case volume, staffing, equipment and clinical support to ensure the safe and effective provision of open-heart surgery. Except as otherwise provided in subsection 2, after*** approval of a service for open-heart surgery is granted, such surgeries must be performed in an approved ***open-heart surgery*** hospital at the following rates:

~~[1.]~~ ***(a)*** Not less than 80 operations during the first 12 months after approval.

~~[2.]~~ ***(b)*** Not less than 150 operations during the second 12-month period after approval.

~~[3.]~~ ***(c)*** Not less than 200 operations during the third and each succeeding 12-month period after approval.

2. The Division may not deny, suspend or revoke approval solely because an approved open-heart surgery hospital fails to perform the number of operations required by subsection 1 during any 12-month period if the hospital demonstrates, in a manner satisfactory to the Division, that:

(a) The hospital participates in the registry of clinical outcomes maintained by the Society of Thoracic Surgeons National Database or an equivalent registry that includes the information specified in NAC 449.61246;

(b) The risk-adjusted clinical outcomes of open-heart surgeries conducted at the hospital are acceptable to the Division when compared with national benchmarks concerning risk-adjusted mortality and major morbidity recognized by the registry in which the hospital participates pursuant to paragraph (a);

(c) The hospital maintains the continuous capacity to perform emergency open-heart surgery procedures 24 hours each day, 7 days each week;

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

(e) The continued provision of open-heart surgery by the hospital is necessary to preserve timely geographic access to care for residents within the region from which the hospital receives referrals.

3. When determining whether an approved open-heart surgery hospital has met the requirements of subsection 2, the Division shall consider:

(a) The risk-adjusted mortality and major morbidity resulting from open-heart surgery conducted at the hospital;

(b) The volume of open-heart surgery procedures conducted at the hospital and the volume of open-heart surgery procedures conducted by each surgeon who performs such procedures at the hospital;

(c) The time it takes for residents within the region from which the hospital receives referrals to travel to the hospital and any barriers to the transportation of such residents to the hospital, including, without limitation, areas that regularly experience hazardous driving conditions in winter and other factors that might prolong transportation time to the hospital;

(d) The availability of alternative approved open-heart surgery hospitals within the region from which the hospital receives referrals;

(e) The transfer capability, emergency coverage and continuity of postoperative care of the hospital; and

(f) The development, submission and execution of any corrective action plan approved by the Division to address identified deficiencies relating to quality of care.

Sec. 25. 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 ***open-heart surgery*** 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 ***open-heart surgery*** hospital to assist in such surgeries; or

(e) ~~[A senior]~~ ***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 ***open-heart surgery*** 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 ***open-heart surgery*** hospital pursuant to NAC 449.358.

Sec. 26. NAC 449.6122 is hereby amended to read as follows:

449.6122 Anesthesia during open-heart surgery at an approved ***open-heart surgery*** 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.

Sec. 27. NAC 449.61222 is hereby amended to read as follows:

449.61222 The registered nurse in charge of the service for open-heart surgery at an approved ***open-heart surgery*** 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.

Sec. 28. NAC 449.61224 is hereby amended to read as follows:

449.61224 1. An approved ***open-heart surgery*** 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.]~~ ***Perfusion.*** 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.

Sec. 29. NAC 449.61226 is hereby amended to read as follows:

449.61226 1. An approved ***open-heart surgery*** 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.

Sec. 30. NAC 449.6123 is hereby amended to read as follows:

449.6123 1. An approved ***open-heart surgery*** 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.

Sec. 31. NAC 449.61232 is hereby amended to read as follows:

449.61232 1. The administration of intensive care units in an approved ***open-heart surgery*** 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.

Sec. 32. NAC 449.61236 is hereby amended to read as follows:

449.61236 An approved ***open-heart surgery*** 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.

Sec. 33. NAC 449.61238 is hereby amended to read as follows:

449.61238 An approved ***open-heart surgery*** 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.

Sec. 34. NAC 449.6124 is hereby amended to read as follows:

449.6124 1. An approved ***open-heart surgery*** hospital ***or a hospital that hosts a level II cardiac catheterization service or level III cardiac catheterization service*** 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.

3. Each cardiac catheterization laboratory shall establish and follow policies for electrical safety that include, without limitation, policies to ensure:

(a) The safety of the primary electrical wiring system;

(b) The electrical isolation of equipment attached to a patient;

(c) The use of an equipotential hardwired grounding system for all equipment; and

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

4. Employees of a cardiac catheterization laboratory shall regularly inspect all equipment used by the laboratory and perform preventive maintenance at least as often as recommended by the manufacturer. The cardiac catheterization laboratory shall maintain records of all such inspection and maintenance.

Sec. 35. NAC 449.61242 is hereby amended to read as follows:

449.61242 An approved ***open-heart surgery*** 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.

Sec. 36. NAC 449.61244 is hereby amended to read as follows:

449.61244 An approved ***open-heart surgery*** 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.

Sec. 37. NAC 449.61246 is hereby amended to read as follows:

449.61246 A registry must be maintained at an approved ***open-heart surgery*** 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 acquity 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.

Sec. 38. NAC 449.61248 is hereby amended to read as follows:

449.61248 An approved ***open-heart surgery*** 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.

Sec. 39. NAC 449.6125 is hereby amended to read as follows:

449.6125 Unless ~~[the]~~ ***an approved open-heart surgery*** 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 approved open-heart surgery hospital shall submit an annual report to the Division. The annual report must include, without limitation, information relating to:

(a) The volume of open-heart surgery procedures performed at the hospital during the immediately preceding year;

(b) The performance of open-heart surgery at the hospital and the quality of care provided to patients of the open-heart surgery service, using indicators designated by the Division;

(c) Risk adjusted mortality, morbidity and other outcomes as specified by the Division; and

(d) The cardiac catheterization laboratory of the hospital and related cardiac catheterization services, including, without limitation, capacity, utilization, staffing and emergency availability as required by the Division.

2. The Division shall conduct an annual off-site review in accordance with NAC 449.61252 to verify compliance with the provisions of NAC 449.612 to 449.61256, inclusive, and sections 2 to 17, inclusive, of this regulation.

3. The Division shall conduct a mandatory on-site inspection of each approved open-heart surgery hospital at least once every 3 years. The Division shall notify the approved open-heart surgery hospital of the composition of the on-site inspection team and the date of the visit to the site.

4. When conducting an on-site inspection pursuant to subsection 3, the Division shall review the services of the hospital for open-heart surgery and related cardiac catheterization services and make findings in accordance with subsection 2 of NAC 449.61208.

Sec. 40. NAC 449.61252 is hereby amended to read as follows:

449.61252 1. ~~[As a part of the]~~ ***The*** annual ~~[inspection]~~ ***off-site review*** of each approved ***open-heart surgery*** hospital ~~[, the Division shall perform a detailed]~~ ***conducted pursuant to NAC 449.6125 must include, without limitation, a*** review of ~~[the]~~ ***:***

(a) The patient files relating to all mortalities at the hospital ~~[.]~~ ***;***

(b) The report submitted pursuant to NAC 449.6125; and

(c) The registry maintained pursuant to NAC 449.61246.

2. In assessing whether a hospital's adjusted rate of mortality is acceptable for the purposes of NAC 449.612 to 449.61256, inclusive, ***and sections 2 to 17, inclusive, of this regulation,*** 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.

Sec. 41. NAC 449.61254 is hereby amended to read as follows:

449.61254 1. If the ***Division determines, after conducting the annual off-site*** 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 17, inclusive, of this regulation, the off-site review indicates an anomaly in a data metric*** 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 ***off-site*** review; or

(b) An ***unscheduled*** on-site inspection,

↳ conducted by one or more of the persons specified in NAC 449.61208. ***An on-site inspection completed pursuant to this subsection must review the services of the hospital for open-heart surgery and related cardiac catheterization services and make findings in accordance with subsection 2 of NAC 449.61208.***

2. When the Division has completed its final review or inspection pursuant to ~~[this]~~ subsection ~~[.]~~ ***1,*** 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 ~~[.]~~ ***1.***

~~[2.]~~ ***3.*** 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 sections 2 to 17, inclusive, of this regulation*** and to carry into effect the recommendations made by the person or persons who conducted the review or inspection pursuant to subsection 1.

~~[3.]~~ ***4.*** 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.

Sec. 42. NAC 449.61256 is hereby amended to read as follows:

449.61256 1. The Division may deny, suspend or revoke its approval ***for the performance of open-heart surgery or cardiac catheterization*** because of the failure of the hospital affected to comply with any provision of NAC 449.612 to 449.61256, inclusive ~~[.]~~ ***, and sections 2 to 17, inclusive, of this regulation.***

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 ~~.~~ ***or performing cardiac catheterization.***

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.