

**ADOPTED REGULATION OF THE DIRECTOR OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**LCB File No. R150-15**

Effective June 28, 2016

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

AUTHORITY: §§1-9, NRS 439A.081.

A REGULATION relating to health facilities; defining the term “letter of approval” for the purposes of those health facility construction projects requiring approval from the Director of the Department of Health and Human Services; interpreting provisions defining a health facility for such projects; revising provisions requiring the provision to the Department of a quarterly progress report on certain health facility construction projects; and providing other matters properly relating thereto.

**Legislative Counsel’s Digest:**

Existing law requires that, in a county whose population is less than 100,000, no person may undertake certain proposed expenditures for new construction by or on behalf of a health facility in excess of \$2,000,000 or such an amount as the Department of Health and Human Services may specify by regulation without first applying for and obtaining the written approval of the Director of the Department. In Senate Bill No. 247, the Nevada Legislature expanded this requirement to apply also in an incorporated city or unincorporated town whose population is less than 25,000 if that city or town is located in a county whose population is 100,000 or more. (NRS 439A.100, as amended by section 2 of Senate Bill No. 247, chapter 422, Statutes of Nevada 2015, at page 2436) Existing regulations provide certain requirements for submitting an application for such a letter of approval. (NAC 439A.365) **Section 2** of this regulation provides a definition for the term “letter of approval,” including an acknowledgment that such a letter is commonly known as a “certificate of need.” **Section 5** of this regulation removes the requirement that the check for the fee required with the application for a letter of approval be a cashier’s check.

Existing law defines “health facility” for the purposes of the requirement for written approval of the Director for certain proposed expenditures, and exempts from that definition “the office of a practitioner used solely to provide routine services for health to the practitioner’s patients.” (NRS 439A.015) **Section 3** of this regulation provides that the Director will interpret the term “routine services for health” to mean “those services that can be rendered to a patient in a practitioner’s office provided that the rendering of such services does not require the construction of a new facility or expansion, renovation or redesign of the existing office at a cost that exceeds, including the cost of equipment acquired for the new facility, expansion, renovation

or redesign, \$2,000,000.” **Section 8** of this regulation makes a conforming change regarding that interpretation in a section that puts the burden of proof on the applicant for demonstrating the relevant criteria for a letter of approval. (NAC 439A.595)

Existing regulations provide requirements for submitting to the Department, prior to applying for a letter of approval, a letter of intent to determine if a letter of approval is required for a certain project. (NAC 439A.305) Existing regulations also require the holder of a letter of approval from the Director to provide the Department with quarterly progress reports on the project that is the subject of the letter of approval. (NAC 439A.465) Finally, existing regulations provide that a letter of approval is subject to withdrawal if the approved timetable of the project is not met by the holder, unless an extension is granted by the Department upon request of the holder. (NAC 439A.475) **Section 6** of this regulation removes the requirement that the provision of information to the Department in a quarterly progress report not be construed or interpreted as a request for an extension or a letter of intent, and **section 7** of this regulation requires that a request for an extension be submitted to the Department in a quarterly progress report.

**Section 1.** Chapter 439A of NAC is hereby amended by adding thereto the provisions set forth as sections 2 and 3 of this regulation.

**Sec. 2.** *“Letter of approval” means a document, commonly known as a certificate of need, which is issued by the Director pursuant to NAC 439A.455 and which indicates the approval of a proposed project for which approval is required pursuant to NRS 439A.100, as amended by section 2 of Senate Bill No. 247, chapter 422, Statutes of Nevada 2015, at page 2436.*

**Sec. 3.** *As used in NRS 439A.015, the Director will interpret the term “routine services for health” to mean those services that can be rendered to a patient in a practitioner’s office provided that the rendering of such services does not require the:*

- 1. Construction of a new facility; or*
  - 2. Expansion, renovation or redesign of the existing office,*
- ↪ at a cost that exceeds, including the cost of equipment acquired for the new facility, expansion, renovation or redesign, \$2,000,000.*

**Sec. 4.** NAC 439A.010 is hereby amended to read as follows:

439A.010 As used in this chapter, unless the context otherwise requires, the words and terms defined in NAC 439A.070 to 439A.240, inclusive, *and section 2 of this regulation* have the meanings ascribed to them in those sections.

**Sec. 5.** NAC 439A.365 is hereby amended to read as follows:

439A.365 1. The original and three copies of an application for a letter of approval must be submitted by mail or delivered by hand to the Department.

2. Each application submitted to the Department must be accompanied by a nonrefundable fee of \$9,500. The fee must be paid by ~~feashier's~~ check made payable to the order of the Department of Health and Human Services.

3. The Department will acknowledge receipt of an application and accompanying fee:

(a) For applications delivered by hand, by a receipt issued to the deliverer at the time of delivery; or

(b) For applications received through the mail, by mail within 5 working days after the date of receipt.

↪ Receipt will be acknowledged on a form of receipt prescribed by the Department.

**Sec. 6.** NAC 439A.465 is hereby amended to read as follows:

439A.465 1. The holder of a letter of approval shall provide the Department with quarterly progress reports, beginning with the first calendar quarter following the issuance of the letter of approval and due no later than 30 days after the end of the quarter. Each progress report must include all of the following:

(a) The date of commencement of the project;

(b) The extent of progress made in complying with the approved timetable, including:

(1) All deadlines which have passed; and

- (2) Whether the required activity met the deadline;
  - (c) Any financial arrangements which differ from those originally approved, including a detailed description of, and the reason for, each difference;
  - (d) The actual cost to date for the project;
  - (e) A revised estimate of the total project cost, including a detailed description and explanation of the differences, if any, between the revised cost and that originally approved;
  - (f) All the steps taken to ensure compliance with each applicable condition;
  - (g) The material changes in the project, including a detailed description and explanation of each change; and
  - (h) The projected date of completion of the project.
2. The Department may, from time to time, request in writing such additional information as is necessary to determine whether the holder of a letter of approval is complying with the letter of approval.
3. The holder of a letter of approval will have 20 working days from his or her receipt of a request for information from the Department to submit the required information in writing. Failure to respond within this period may constitute grounds for the Department to initiate withdrawal proceedings pursuant to NAC 439A.505.
4. The holder of a letter of approval must provide access to the project site and all project records to the Department's staff for examination and inspection in order to verify compliance with the letter of approval and any information submitted by the holder of the letter of approval.
- ~~5. The provision of information through progress reports required by the Department will not be construed or interpreted as an application for extension pursuant to NAC 439A.475 or the notification required pursuant to NAC 439A.305.~~

**Sec. 7.** NAC 439A.475 is hereby amended to read as follows:

439A.475 1. A letter of approval is subject to withdrawal pursuant to NAC 439A.505 if the approved timetable is not met by the holder of the letter of approval, unless an extension is granted by the Department pursuant to this section.

2. An extension will be granted only if the applicant manifests an intention to complete the project and demonstrates that good and sufficient reasons exist for its failure to meet the timetable. Good and sufficient reasons include delays caused by:

- (a) Litigation;
- (b) The actions of a regulatory agency other than the Department; or
- (c) An event determined by the Department to be beyond the control of the holder of the letter of approval.

3. Except as otherwise provided in subsection 4, a request for an extension must be submitted to the Department *as part of the quarterly progress report required by NAC 439A.465* at least 90 days before the required date of completion of the project. The request must contain information setting forth the reasons for noncompliance with the timetable and the extent of the progress toward completion of the project.

4. A request for an extension of a letter of approval which is submitted less than 90 days before the required date of completion of the project will not be accepted unless the applicant can demonstrate to the satisfaction of the Department that unforeseen occurrences prevented a timely submission.

5. Within 20 working days after receipt of the request, the Director will determine whether or not to grant an extension.

6. If the decision is to grant an extension, the Director will issue a letter of extension to the holder of the letter of approval, which will contain:

- (a) The reasons for granting the extension; and
- (b) A revised timetable for the project, including a revised date of completion for the project.

7. If an extension is not granted, proceedings to withdraw the letter of approval may be initiated pursuant to NAC 439A.505.

**Sec. 8.** NAC 439A.595 is hereby amended to read as follows:

439A.595 1. The applicant for a letter of approval has the burden of proof to satisfy all applicable criteria for review contained in NAC 439A.605 to 439A.637, inclusive.

2. A finding that the applicant has failed to meet its burden of proof regarding an applicable criterion will be made if:

(a) The applicant fails to provide sufficient, relevant, demonstrative evidence for a favorable determination; or

(b) The evidence on the record opposing the application outweighs the evidence in support of the application regarding the criterion.

3. The criteria for review are applicable to a proposed project if the project includes the construction , *expansion, renovation, redesign* or establishment of a facility to provide health services ~~1, except for a facility which will be used solely for the offices of practitioners of health care.~~ *at a cost that is proposed to exceed, including the cost of equipment acquired for the new facility, expansion, renovation or redesign, \$2,000,000.*

4. If an application is denied on the basis of these criteria, the written findings of fact must clearly state the reason for that denial.

**Sec. 9.** NAC 439A.338 is hereby repealed.

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## TEXT OF REPEALED SECTION

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**439A.338 Capital expenditures for which approval not required; determination of cost of new construction subject to letter of approval.** (NRS 439A.081, 439A.100)

1. The provisions of subsection 1 of NRS 439A.100 are applicable only to a project which is not dependent on or related to a larger single project.
2. The cost for construction in which no new square footage is added is not subject to a letter of approval. The cost of construction related to the existing space must be deducted from the total capital expenditure to determine the cost of the new construction subject to a letter of approval.
3. The cost of construction attributed to space for a medical office building or an office for a health practitioner to be used solely to provide routine health services as defined in NRS 439A.017 must be deducted from the total capital expenditures to determine the cost of new construction subject to a letter of approval.

**Department of Health and Human Services**  
**Director's Office**  
**Certificate of Need**  
**LCB File No. R150-15**

**Informational Statement per NRS 233B.066**

1. A clear and concise explanation of the need for the adopted regulation;
  - *Statutory changes were made to the Certificate of Need program in the 2015 Legislative Session. Subsequently, proposed changes were drafted to update the corresponding regulations. Stakeholders requested additional changes through the public workshop process, which were adopted by the Director through the public hearing. The resulting changes include the following:*
    - *Add definition of "Letter of Approval" to reference Certificate of Need;*
    - *Interpret "routine services for health" to exclude services that require construction of a new facility or expansion, renovation or redesign of the existing office at a cost that exceeds \$2,000,000;*
    - *Remove requirement for cashier's check under NAC 439A.365;*
    - *Allow requests for extension to be communicated through a quarterly report under NAC 439A.465 and 439A.475;*
    - *Remove exception for a facility which will be used solely for the offices of practitioners of health care under NAC 439A.595; and*
    - *Repeal section on capital expenditures for which approval is not required under NAC 439A.338.*
2. A description of how public comment was solicited, a summary of public response, and an explanation how other interested persons may obtain a copy of the summary;
  - *Public comment was solicited through two online surveys for the small business impact questionnaire, as well as three public workshops and one public hearing, noticed through website postings, multiple electronic mailings to stakeholders, and hard copy mailings to state and county libraries for public posting.*
  - *All comments received came from health care facilities representatives, and are summarized under item #4, below, for businesses.*
  - *Response documentation is available through the Department of Health and Human Services, Primary Care Office via email to [ljhale@health.nv.gov](mailto:ljhale@health.nv.gov) or via telephone request at (775) 684-4041.*
3. A statement indicating the number of persons who attended each meeting or workshop, testified at each hearing, and submitted written statements regarding the proposed regulation. This statement should include for each person identified pursuant to this section that testified at each hearing and/or submitted written statements regarding the proposed regulation, the following information, if provided to the agency conducting the hearing or workshop:



**December 15, 2015 Workshop**

	<b>Name</b>	<b>Organization</b>	<b>Phone</b>	<b>Email</b>	<b>Support</b>
1	Blayne Osborn	NV Rural Hospital Partners	775-827-4770	blayne@nrhp.org	Y
2	Judy Guzman	Children's Specialty Center of NV	702-862-1123	jguzman@cure4thekids.org	Neutral
3	Gerald Ackerman	NV Office of Rural Health	775-738-3828x22	gackerman@medicine.nevada.edu	Y

**January 28, 2016 Workshop**

	<b>Name</b>	<b>Organization</b>	<b>Phone</b>	<b>Email</b>	<b>Support</b>
1	Parker Stremmel	Ferrari Public Affairs	(Not provided)	parker@ferraripa.com	Neutral
2	Blayne Osborn	NV Rural Hospital Partners	775-827-4770	blayne@nrhp.org	Y
3	Bill Welch	NV Hospital Association	775-827-0184	bill@nvha.net	Neutral
4	Rob Fuller	Mesa View Regional Hospital	(Not provided)	Robert.fuller@mesaviewhospital.com	Y
5	Patty Holden	Mesa View Regional Hospital	(Not provided)	pattyholden@mesaviewhospital.com	Y

**April 12, 2016 Workshop**

	<b>Name</b>	<b>Organization</b>	<b>Phone</b>	<b>Email</b>	<b>Support</b>
1	Jason Bleak	Grover C. Dils Medical Center	775-726-3171	jkbleak@gcdmc.org	Y
2	Patricia Bianchi	Pershing General Hospital	775-273-2621	pbianchi@pershinghospital.org	Y
3	Joan Hall	NV Rural Hospital Partners	775-827-4770	joan@nrhp.org	Y
4	Kelly Adams	Desert View Hospital	775-751-7529	Kelly.adams@dvrhc.org	Y
5	Bill Welch	NV Hospital Association	775-827-0184	bill@nvha.net	Y
6	Thomas Maher	Boulder City Hospital	702-291-4111	tmaher@bouldercityhospital.org	Y
7	Blayne Osborn	NV Rural Hospital Partners	775-827-4770	blayne@nrhp.org	Y
8	Judy Newland	Incline Hospital	Not Provided	(Participated via call-in)	Y
9	Patty Holden	Mesa View Hospital	Not Provided	(Participated via call-in)	Y
10	Matt Walker	William B. Ririe Hospital	Not Provided	(Participated via call-in)	Y
11	Peggy Lindsey	Battle Mountain General Hospital	Not Provided	(Participated via call-in)	Y

**May 16, 2016 Hearing**

	<b>Name</b>	<b>Organization</b>	<b>Phone</b>	<b>Email</b>	<b>Support</b>
1	Joan Hall	NV Rural Hospital Partners	775-827-4770	joan@nrhp.org	Y
2	Blayne	NV Rural Hospital	775-827-4770	blayne@nrhp.org	Y

	Osborn	Partners			
3	Bill Welch	NV Hospital Association	775-827-0184	bill@nvha.net	Y
4	Joanna Jacob	Ferrari Public Affairs for Davita HealthCare Partners	775-351-8978	joanna@ferraripa.com	Neutral
5	Rob Fuller	Mesa View Hospital	Not Provided	(Participated via call-in)	Y
6	Hoyt Skabelund	Banner Churchill Hospital	Not Provided	(Participated via call-in)	Y

### Written Statements and Letters of Support

	Name	Organization	Phone	Format	Support
1	Hoyt Skabelund	Banner Churchill Hospital	Not Provided	e-mail via NV Rural Hospital Partners and Letter of Support	Y
2	Toni Inserra	South Lyon Medical Center	Not Provided	e-mail via NV Rural Hospital Partners	N
3	Rick Palagi	Northeastern Nevada Regional Hospital	775-738-5151	Letter of Support	Y
4	Richard Munger	Mt. Grant General Hospital	775-945-2461	Letter of Support	Y
5	Thomas Maher	Boulder City Hospital	702-293-4111	Letter of Support	Y
6	Patty Holden	Mesa View Regional Hospital	702-345-4280	Letter of Support	Y
7	Matthew Walker	William B Ririe Hospital	Not Provided	Letter of Support	Y
8	Peggy Lindsey	Battle Mountain General Hospital	775-635-2550	Letter of Support	Y
9	Jason Bleak	Grover C. Dils Medical Center	Not Provided	Survey Response	Y

4. A description of how comment was solicited (i.e., notices) from affected businesses, a summary of their response, and an explanation how other interested persons may obtain a copy of the summary.
  - *Public comment was solicited through two online surveys for the small business impact questionnaire, as well as three public workshops and one public hearing, noticed through website postings, multiple electronic mailings to stakeholders, and hard copy mailings to state and county libraries for public posting.*
  - *Following the first public workshop, representatives for Nevada Rural Hospital Partners and Nevada Hospital Association proposed revised language to remove the exclusion for physician-owned facilities. Subsequently, revised regulations were drafted and distributed to stakeholders for comment.*
  - *Letters of support were received from several rural hospitals, with the following key statements:*
    - *The proposed regulation will provide much needed guidance and clarify the ambiguous nature governing the \$2,000,000 capital expenditure limit for health facility construction and equipment projects. . . Without the proposed clarification, a variety of medical or diagnostic clinics could skirt the current CON process [and] threaten existing medical providers, particular those in rural areas.*

- *The state's CON construct should be fair and consistent in its applicability across all providers. The current interpretation that allows for a "medical office building or an office of a health practitioner to be used solely to provide routine health services. . ." to be exempt from the CON process places the government in the position of choosing winners and losers in the private marketplace.*
  - *The proposed regulation does not limit innovation or stifle competition. It simply ensures the continuation of a level playing field for all health care providers.*
  - *As CEO of Boulder City Hospital, I am acutely aware of the threat this regulation without the proposed changes can have on the only independent non-profit hospital in Nevada that is not part of a larger corporate structure nor is eligible to receive tax or mining subsidies.*
  - *When a large business comes in to provide services, they rarely offer the services to everyone. Instead they offer it to the insured and not the uninsured or underinsured. . . This shift means we take on a larger responsibility of absorbing the cost . . .and will be forced to limit services or go out of business.*
  - *The following statements were received via email and survey responses from health care facilities:*
    - *CON regulations protect our small hospital district allowing for long term operations. As a small county hospital service approximately 4000 residents, the introduction of other health service that would undercut our services will make it more difficult if not impossible to continue operation.*
    - *Potential to save a few hundred thousand by not oversaturating the market leading to all facilities census dropping.*
    - *(Indicating indirect beneficial effects) Prevents duplication of services that would raise our cost per unit of service. We treat Medicaid patients and uninsured patients while many boutique outpatient service providers that could enter the market would not.*
    - *(Indicating indirect adverse effects)With master planning including the construction of a stick built building to replace our temporary modular clinic in the near future, this additional restriction will not only increase cost but the time for completion.*
  - *Response documentation is available through the Department of Health and Human Services, Primary Care Office via email to [ljhale@health.nv.gov](mailto:ljhale@health.nv.gov) or via telephone request at (775) 684-4041.*
5. If, after consideration of public comment, the regulation was adopted without changing any part of the proposed regulation, a summary of the reasons for adopting the regulation without change. The statement should also explain the reasons for making any changes to the regulation as proposed.
- *The changes proposed by stakeholders were made to the regulation and adopted by the Director for the Department of Health and Human Services.*
  - *These changes support the Department's statutory function under NRS 439A.081 to provide for the effective use of methods for controlling increases in the cost of health care; providing for the adequate supply and distribution of health resources; providing for equal access to health care of good quality at a reasonable cost; and providing*

*education to the public regarding proper personal health care and methods for the effective use of available health services.*

6. The estimated economic effect of the regulation on the business which it is to regulate and on the public. These must be stated separately, and in each case must include:
  - (a) Both adverse and beneficial effects; and
  - (b) Both immediate and long term effects.
  - *The Certificate of Need (CON) is required for projects costing \$2 million or more, in rural communities, and there is an application fee of \$9,500 for the state's review, hearing and oversight process. For existing health facilities, the CON supports sustainability by requiring that new construction proposals must document need, financial feasibility, and effect on the cost of health care. The immediate effect is the cost of the application and the opportunity for the state, the public and other stakeholders to review the proposed project. The long-term effect is to stabilize access to and cost of health care in rural communities.*
7. The estimated cost to the agency for enforcement of the proposed regulation.
  - *Funding for the agency to administer the CON program is fully supported by the application fees.*
8. A description of any regulations of other state or government agencies which the proposed regulation overlaps or duplicates and a statement explaining why the duplication or overlapping is necessary. If the regulation overlaps or duplicates a federal regulation, name the regulating federal agency.
  - *This regulation does not overlap or duplicate any other state or government agency regulations.*
9. If the regulation includes provisions which are more stringent than a federal regulation which regulates the same activity, a summary of such provisions; and
  - *There are no federal regulations that regulate this activity.*
10. If the regulation establishes a new fee or increases an existing fee, a statement indicating the total annual amount the agency expects to collect and the manner in which the money will be used.
  - *The regulation does not establish a new fee nor does it increase the existing fee.*