ADOPTED REGULATION OF THE

STATE BOARD OF HEALTH

LCB File No. R203-09

Effective July 22, 2010

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

AUTHORITY: §1, NRS 449.037 and 449.445.

A REGULATION relating to surgical centers for ambulatory patients; prescribing requirements for accreditation by a nationally recognized organization; and providing other matters properly relating thereto.

- **Section 1.** NAC 449.9745 is hereby amended to read as follows:
- 449.9745 *1*. The operator of an ambulatory surgical center shall the deemed by the Division to have complied with the requirements for licensing contained in NAC 449.971 to 449.996, inclusive, if:
- 1. The center is currently accredited by the]:
- (a) Not later than 6 months after obtaining a license, submit proof to the Division of accreditation by:
 - (1) The Joint Commission [on Accreditation of Health Care Organizations, the];
 - (2) The Accreditation Association for Ambulatory Health Care for the ;
 - (3) The American Association for Accreditation for Ambulatory Surgery Facilities; or
- (4) Any other nationally recognized organization approved by the State Board of Health pursuant to subsection 3; and
 - (b) Maintain current accreditation during the term of licensure.

- 2. The operator [provides] of an ambulatory surgical center shall provide to the Division [with evidence of the accreditation; and] each report provided by the accrediting organization, including, without limitation, the initial report, each report issued upon renewal of an accreditation and any other report issued by the accrediting organization.
- 3. [The standards for accreditation applied by the accrediting organization are at least as stringent as the requirements of NAC 449.971 to 449.996, inclusive.] An organization which accredits ambulatory surgical centers that wishes to be recognized by the State Board of Health as an accrediting organization for purposes of this section must submit to the Division an application on a form prescribed by the Division. The Division shall review each application received pursuant to this subsection and shall forward to the State Board of Health each application, including the recommendation of the Division whether to approve or deny the application. The recommendation of the Division must be based upon whether the applicant requires an ambulatory surgical center to meet the minimum requirements necessary to ensure a high level of quality. The State Board of Health may approve or deny an application submitted pursuant to this subsection.

HEALTH DIVISION

Bureau of Health Care Quality and Compliance Health Facilities Program June 18, 2010 LCB File # R203-09

Information Statement per NRS 233B.066

1. 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.

Before drafting the regulations, the agency met with stakeholder groups. Then draft regulations were developed and all licensed and pending ambulatory surgery centers were mailed a copy of the proposed draft regulations along with a small business impact questionnaire. The mailing also identified the date, time and place for the public workshop. The public workshops were properly noticed in accordance with open meeting requirements and all interested parties were given an opportunity to provide comments before, during and after the public workshops which occurred in September of 2009. After the workshops the agency accepted written comments until a final draft of the regulations was provided to LCB. Minutes from the public workshops are attached.

- 2. The number of persons who:
 - (a) Attended the hearing;
 - (b) Testified at each hearing; and
 - (c) Submitted to the agency written statements.

The number of persons who attended the June 18, 2010 hearing

Las Vegas = 52

Carson City = 55

Testified = 0

The number of persons who attended the public workshops:

Las Vegas = 17

Carson City = 12

The number of persons who testified at the public workshops:

Las Vegas = 7

Carson City = 5

The number of person who submitted written statements to HCQC = 2

3. A description of how comment was solicited from affected businesses, a summary of their response, and an explanation how other interested persons may obtain a copy of the summary.

All licensed and pending ambulatory surgery centers were mailed a copy of the proposed draft regulations along with a small business impact questionnaire. Responses to the small business impact questionnaire were summarized and a small business impact statement was generated, a

copy of that summary is attached. Interested individuals may contact the Bureau of Health Care Quality and Compliance to obtain a copy of the summary.

4. If 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 proposed regulation was adopted without any changes or errata.

The Institute for Medical Quality asked to be added to the list of approved accrediting organizations. Whereas a representative from the ASC association indicated, there should be some kind of review prior to approving additional accrediting organizations to the list. Hence, the regulations address a process for new accrediting organizations to apply for approval by the Board. This allows for the currently licensed ASCs to continue their accreditation with the already approved organizations, yet allows for new organizations to become approved and then for ASCs to use those organizations for accreditation in the future.

The bureau considered all comments and attempted to ensure compliance with the statutory requirements while not arbitrarily burdening the industry, in drafting the language of these regulations.

- 5. 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.

Estimated economic effect:

- (a) BHCQC has determined that the adoption of these regulations will create an economic impact on surgical centers for ambulatory patients, because they establish new fees. BHCQC has attempted to minimize this affect by assessing fees at 2 times the current rate even though the facilities will be inspected every year, as opposed to 1 time every 6 years. These fees will be evaluated during the next biennium to determine whether they are sufficient to cover the cost of agency services. New initial licensure fees have been set at \$7,140 and new renewal fees at \$3,570, for surgical centers for ambulatory patients. The regulations will impose a burden upon small businesses, but will not directly restrict the formation, operation, or expansion of a small business in Nevada. A small business is defined in Nevada Revised Statutes (NRS) 233B as a "business conducted for profit which employs fewer than 150 full-time or part-time employees."
- (b) The proposed changes should have a beneficial effect on the public. The proposed changes describe the accreditation requirements in accordance with AB 123 and establish additional protections for patients.
- 6. The estimated cost to the agency for enforcement of the proposed regulation.

A fiscal note attached to AB 123 during the legislative session estimated the cost to BHCQC at \$257,236 in the 2009-2010 fiscal year and \$442,403 in the 2010-2011 fiscal year. These costs included 2.0 FTE in 2009-2010 for outpatient settings and 1.0 FTE in 2010-2011 for outpatient settings. The costs also included 1.0 FTE in 2009-2010 for surgery centers and .5 FTE in 2010-2011 for surgery centers. So there's a total of 4.5 FTE between the two facility types for the two fiscal years. Out of the 4.5 FTE, 1.5 are associated with surgery centers and 3.0 FTE are associated with outpatient settings. Or approximately 33.3% of the costs are associated with surgery centers and 66.6% of the costs are associated with outpatient settings. So for 2009-2010 the additional cost for surgery centers would be \$85,659 and for 2010-2011 the additional cost for surgery centers would be \$147,320.

These costs were based on rudimentary analysis of the legislation and associated workload. The fees were established to offset the cost of the workload for ambulatory surgery centers and will be adjusted based on actual costs.

7. 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.

These regulations do not represent duplication on local or federal levels. The Nevada State Board of Health is responsible for generating regulations for this facility type concerning accreditation and there is no equivalent responsibility on the local or federal level.

8. If the regulation includes provisions which are more stringent than a federal regulation which regulates the same activity, a summary of such provisions.

CMS's federal regulations do not require accreditation of ambulatory surgery centers.

9. If the regulation provides a new fee or increases an existing fee, the total annual amount the agency expects to collect and the manner in which the money will be used.

The total amount anticipated to be collected in 2009-2010 fiscal year is \$214,200 (approx. 100% of the total possible applicants are anticipated to apply for renewal in this period ($60 \times 3,570 = 214,200$). The total amount anticipated to be collected in 2010-2011 fiscal year is \$214,200 (approximately 100% of the total possible applicants are anticipated to apply for renewal in this period ($60 \times 3,570 = 214,200$). Money collected will be used to process applications, conduct surveys and complaint investigations in surgical centers for ambulatory patients and unlicensed facilities.

10. If the proposed regulation is likely to impose a direct and significant economic burden upon a small business or directly restrict the formulation, operation or expansion of a small business. What methods did the agency use in determining the impact of the regulation on a small business?

All licensed and pending ambulatory surgery centers were mailed a copy of the proposed draft regulations along with a small business impact questionnaire. It was determined that the adoption of these regulations will create an economic impact on surgical centers for ambulatory patients, because they establish new fees, but will not directly restrict the formation, operation, or expansion of a small business in Nevada. BHCQC has attempted to minimize this affect by assessing fees at 2 times the current rate even though the facilities will be inspected every year, as opposed to 1 time every 6 years. These fees will be evaluated during the next biennium to determine whether they are sufficient to cover the cost of agency services.