ADOPTED REGULATION OF THE

STATE BOARD OF HEALTH

LCB File No. R170-12

Effective October 4, 2013

(Note: This regulation is composed of some of the provisions from LCB File No. 181-09P relating to ambulatory surgical centers)

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

AUTHORITY: §§1-6, NRS 449.0302.

A REGULATION relating to medical facilities; revising provisions governing ambulatory surgical centers; and providing other matters properly relating thereto.

Section 1. NAC 449.980 is hereby amended to read as follows:

449.980 The governing body shall ensure that:

- 1. Each patient of the center is under the care of a physician.
- 2. [Each] Except as otherwise provided in this subsection, each patient admitted to the center receives a presurgical evaluation conducted by a physician within the 7 days immediately preceding the date of the patient's surgery. A podiatric physician licensed pursuant to chapter 635 of NRS may conduct the presurgical evaluation for a podiatric patient.
- 3. A physician is on the premises of the ambulatory surgical center and immediately available at all times when there are patients in the operating rooms or the recovery room of the center. As used in this subsection, "immediately available" means the physician is [sufficiently free from other duties to be] able to respond rapidly to an emergency.
 - 4. An annual operating budget and a plan for capital expenditures are established.
 - 5. The center is adequately staffed and equipped.

- 6. There is documentation in the files of the center of:
- (a) The qualifications of all persons under contract with the center; and
- (b) Whether such persons who work at the center and have exposure to patients have been screened for communicable diseases as described in NAC 441A.375.
- 7. The center establishes and maintains a program for the prevention and control of infections and communicable diseases as required pursuant to NAC 449.98452.
- 8. The center adopts, enforces and at least annually reviews written policies and procedures required by NAC 449.971 to 449.996, inclusive, including an organizational chart. These policies and procedures must:
 - (a) Be approved annually by the governing body.
- (b) Provide that a surgical procedure may be performed on a patient only with the consent of the patient or the patient's legal representative, except in an emergency.
- (c) Include procedures for the periodic review and amendment, as deemed appropriate, of the scope of the procedures performed at the center.
 - **Sec. 2.** NAC 449.9835 is hereby amended to read as follows:
- 449.9835 1. If a licensee is a *sole* physician operator, the ambulatory surgical center operated by the licensee is not required to have a governing body or an administrator. In such a case, in the absence of a governing body or an administrator, the *sole* physician operator is responsible for complying with all the provisions of NAC 449.971 to 449.996, inclusive.
- 2. As used in this section, ["physician] "sole physician operator" means a physician, a podiatric physician licensed pursuant to chapter 635 of NRS or a dentist licensed pursuant to chapter 631 of NRS who is operating an ambulatory surgical center for the purpose of performing surgery only upon his or her patients.

- **Sec. 3.** NAC 449.989 is hereby amended to read as follows:
- 449.989 The medical record of each patient must be complete, authenticated, accurate and current, and must include the following information:
- 1. A complete identification of the patient, including information on his or her next of kin and on the person or agency legally or financially responsible for him or her.
 - 2. A statement concerning the admission and diagnosis of the patient.
 - 3. The medical history of the patient.
- 4. Documentation that the patient has been given a presurgical evaluation conducted by a physician *or a podiatric physician licensed pursuant to chapter 635 of NRS, as applicable,* within the 7 days immediately preceding the date of the patient's surgery.
 - 5. Evidence of any informed consent given for the care of the patient.
- 6. Any clinical observations of the patient, such as the notes of a physician, a nurse or any other professional person in attendance. Such an entry must be signed by the person making the entry and include the title of that person.
 - 7. Reports of all studies ordered, including laboratory and radiological examinations.
 - 8. Confirmation of the original diagnosis, or the diagnosis at the time of discharge.
 - 9. A report of any operation performed on the patient, prepared by the surgeon.
- 10. A description of the procedure followed in any administration of anesthesia to the patient.
 - 11. A recovery report for the patient.
- 12. A summary of discharge, including, without limitation, the disposition of the patient and any recommendations and instructions given to the patient.

- 13. Documentation that a member of the nursing staff interviewed the patient within 72 hours after the patient was discharged from the center to determine the condition of the patient and whether the patient was satisfied with the services provided, and to receive any complaints or problems the patient may have.
 - **Sec. 4.** NAC 449.9902 is hereby amended to read as follows:
 - 449.9902 1. An ambulatory surgical center must be equipped with:
 - (a) A cardiac defibrillator;
 - (b) A tracheostomy set; and
- (c) Such other emergency medical equipment and supplies as are specified by the members of the medical staff.
- 2. A person trained in the use of emergency equipment and in cardiopulmonary resuscitation must be on the premises of the ambulatory surgical center and immediately available at all times when there is a patient in the center. As used in this subsection, "immediately available" means that the person is [sufficiently free from other duties to be] able to respond rapidly to an emergency.
 - **Sec. 5.** NAC 449.9935 is hereby amended to read as follows:
- 449.9935 1. The operating and recovery rooms of an ambulatory surgical center must be used exclusively for surgical procedures.
- 2. Except as otherwise provided in subsection 3, surgical procedures must be conducted in a class A, B or C operating room in accordance with chapter 9 of the *Guidelines for Design and Construction of Hospital and Health Care Facilities*, adopted by reference pursuant to NAC 449.0105.

- 3. If an ambulatory surgical center is licensed to perform only endoscopic procedures, such procedures may be conducted in an endoscopy suite in accordance with chapter 9 of the *Guidelines for Design and Construction of Hospital and Health Care Facilities*, adopted by reference pursuant to NAC 449.0105.
 - 4. A registered nurse experienced in surgical procedures shall supervise the operating room.
 - 5. Only a registered nurse may function as the circulating nurse in the operating room.
 - 6. The operating room must be equipped with:
 - (a) A system for making emergency calls;
 - (b) Oxygen;
- (c) Mechanical ventilatory assistance equipment, including, without limitation, a manual breathing bag and a ventilator;
 - (d) Cardiac monitoring equipment;
 - (e) Laryngoscopes and endotracheal tubes; and
 - (f) Suction equipment.
- 7. If the operating team consists of persons who are not physicians, [such as a dentist, a podiatrist or a nurse,] a physician must be on the premises and immediately available in case of an emergency. As used in this subsection, "immediately available" means the physician is [sufficiently free from other duties to be] able to respond rapidly to the emergency.
 - **Sec. 6.** NAC 449.994 is hereby amended to read as follows:
- 449.994 1. A presurgical evaluation conducted by a physician *or a podiatric physician licensed pursuant to chapter 635 of NRS, as applicable*, and the pertinent past medical history of a patient must be recorded in the chart of the patient before surgery.

2. A properly executed form of consent to surgery must be placed in the medical record of						
the patient before surgery. A report must be prepared immediately after surgery describing the						
technique and findings of the surgery.						

DIVISION OF PUBLIC AND BEHAVIORAL HEALTH March 8, 2013 LCB File # R170-12

Information Statement per NRS 233B.066

1. A clear and concise explanation of the need for the adopted regulation.

Industry has expressed that the inability for podiatrists to conduct their pre-surgical evaluations on their patients in ambulatory surgical centers has resulted in delayed wait times for patients to receive needed surgeries and has resulted in increased costs for patients. In rural areas, such as Elko, it has been expressed that it is a burden to find a physician to conduct the pre-surgical evaluations for podiatric patients. This burden would be eliminated if podiatrists would be able to perform the pre-surgical evaluations on their patients. Podiatrists, the Board of Podiatry, ambulatory surgical centers and the Nevada Ambulatory Surgery Center Association have all expressed support in these proposed regulations to allow podiatrists to conduct pre-surgical evaluations for podiatric patients in ambulatory surgical centers. The Board of Podiatry has confirmed that it is within the scope of practice of podiatrists to perform the pre-surgical evaluations of their patients.

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 by the Notice of Public Hearing posted at Division of Public and Behavioral Health locations, State Library and Archives, county libraries and mailed notification of the Notice of Public Hearing to affected stakeholders. A public workshop was held in Carson City and Las Vegas via videoconference on September 19, 2012. The following is a summary of the testimony provided during the State Board of Health Public Hearing on March 8, 2013:

A public hearing was held on December 14, 2012 before the Board in which the Board expressed concerns that the proposed regulations would expand the scope of practice of a podiatrist.

The Division of Public and Behavioral Health went back to the original request of the Board of Podiatry which asked that podiatrists be able to conduct the pre-surgical evaluations for their patients. The Division of Public and Behavioral Health received agreement from the Board of Podiatry to do the following:

- 1. Remove podiatrists from the ambulatory surgical center definition of a physician in Section 1 of LCB File No. R170-12; and
- 2. Add language to the proposed regulations which would allow podiatrists to conduct presurgical evaluations for podiatric patients in ambulatory surgical centers.

The Board of Health approved the errata that addressed the Board of Podiatry's request that podiatrists be able to conduct pre-surgical evaluations on their patients and removed language that would broaden the scope of practice of a podiatrist.

No one testified for or in opposition to the proposed regulations.

A summary of the Hearing for Amendment of Nevada Administrative Code (NAC) 449, "Medical and Other Related Facilities" can be obtained by contacting the Division of Public and Behavioral Health, 727 Fairview Drive, Suite E, Carson City, Nevada, 89701.

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

Eleven people attended the hearing. Leticia Metherell, Health Facilities Inspection Manager for the Division of Public and Behavioral Health presented the proposal and errata to amend Nevada Administrative Code, (NAC) 449, "Medical and Other Related Facilities". No one testified for or in opposition. A summary of the testimony can be found in number 1 above. No one provided written statements at the public hearing.

4. 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.

A small business impact questionnaire and workshop notice which included information on how to obtain a copy of the proposed regulations was sent to ambulatory surgical centers. The workshop notice and draft regulations were also posted on the Division of Public and Behavioral Health's website, distributed through the Division of Public and Behavioral Health's List Serv and posted in accordance with open meeting law. Out of 57 small business impact questionnaires distributed, only 3 responses were received. The following is a summary of the 57 responses:

Summary of Response

Summary of Comments Received (3 responses were received out of 57 small business impact questionnaires distributed)						
Will a specific regulation have an adverse economic effect upon your business?	Will the regulation (s) have any beneficial effect upon your business?	Do you anticipate any indirect adverse effects upon your business?	Do you anticipate any indirect beneficial effects upon your business?			
No – 3 responses Yes – 0 responses	No – 2 responses Yes – 1 responses	No – 3 responses Yes – 0 responses	No – 3 responses Yes – 0 responses			
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Comments:	Comments: Has no podiatrist on staff and has no plans, at present, to bring any on.	Comments: Has no podiatrist on staff and has no plans, at present, to bring any on.	Comments: Has no podiatrist on staff and has no plans, at present, to bring any on.			

If po	diatrists are able to	
writ	e H&P's patients	
wou	d spend less time	
and	financial resources	
bein	g cleared for	
surg	ery.	

Number of Respondents out 57	Adverse economic effect?	Beneficial effect?	Indirect adverse effects?	Indirect beneficial effects?
3	0	1	0	0

A summary of the Hearing for Amendment of Nevada Administrative Code (NAC) 449, "Medical and Other Related Facilities", LCB File No. R170-12 can be obtained by contacting the Division of Public and Behavioral Health, 727 Fairview Drive, Suite E, Carson City, Nevada 89701.

5. 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.

A public hearing was held on December 14, 2012 before the Board in which the Board expressed concerns that the proposed regulations would expand the scope of practice of a podiatrist and were tabled for the March 2013 Board of Health hearing.

The Division of Public and Behavioral Health went back to the original request of the Board of Podiatry which asked that podiatrists be able to conduct the pre-surgical evaluations for their patients. The Division of Public and Behavioral Health received agreement from the Board of Podiatry to move forward regulations which would allow podiatrists to perform the pre-surgical evaluations.

- 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:
 - Beneficial effects: It will have a beneficial effect on ambulatory surgical centers in which podiatrists practice as it will allow podiatrists to perform pre-surgical evaluations. This will increase efficiencies for those centers.
 - Adverse effects: None Anticipated.
- b. Both immediate and long term effects.
 - Immediate effects: Cost savings to patients as podiatrist will be able to do history and physical thus eliminating the cost of another physician conducting it, reduced wait times for patients to undergo surgery and increased patient safety as a result of patients being able to obtain the care they need in a more efficient and timely manner.

- Long term effects: Cost savings to patients as podiatrist will be able to do history and physical thus eliminating the cost of another physician conducting it, reduced wait times for patients to undergo surgery and increased patient safety as a result of patients being able to obtain the care they need in a more efficient and timely manner.
- 7. The estimated cost to the agency for enforcement of the proposed regulation.

The estimated cost to the agency for enforcement of the proposed regulations is \$0.

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 regulatory federal agency.

The Centers for Medicare and Medicaid's (CMS) federal regulations allow podiatrists to conduct the pre-surgical evaluation of patients in ambulatory surgical centers. The overlapping is necessary because CMS participation is voluntary therefore there may be instances when an ambulatory surgical center only holds a state license (is not Medicare Certified) and therefore would not be held to the federal regulations.

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

The regulation allowing a podiatrist to conduct a pre-surgical evaluation in not more stringent than the federal regulation which also allows it.

10. 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.

There is no new fee or increase of an existing fee associated with the proposed regulations.

11. 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?

There is no direct or significant economic burden on businesses. The Division of Public and Behavioral Health sent a small business impact questionnaire to ambulatory surgical centers and none responded that it would create a burden. One business representative responded: "If podiatrists are able to write H&P's patients would spend less time and financial resources being cleared for surgery." H&P's are the pre-surgical histories and physicals performed on patients. The Nevada Ambulatory Surgery Center Association is also in support of podiatrists being able to perform the pre-surgical evaluations on their patients.