ADOPTED REGULATION OF THE

STATE BOARD OF HEALTH

LCB File No. R075-04

Effective August 5, 2004

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

AUTHORITY: §1, NRS 439.150, 449.037 and 449.050; §§2-7, NRS 449.037.

A REGULATION relating to facilities for the treatment of irreversible renal disease; increasing the fee for an application to increase the number of stations for which a facility is licensed; adopting by reference certain standards for the analysis of certain water in facilities; requiring facilities to comply with such standards; requiring a facility to ensure that adequate water is available to the essential areas of the facility; and providing other matters properly relating thereto.

Section 1. NAC 449.520 is hereby amended to read as follows:

449.520 1. A facility shall notify the Bureau in writing at least 30 days before beginning any construction, renovation or modification of the physical plant of the facility.

2. A facility must obtain the approval of the Bureau before increasing the number of stations for which the facility is licensed. If a facility intends to increase the number of those stations, the facility must, at least 30 days before the proposed date to increase the number of stations, submit to the Bureau an application for a new license. The application must be submitted on a form approved by the Bureau and include:

(a) Evidence satisfactory to the Bureau that:

(1) The facility has reviewed the availability of the members of the staff of the facility and, if necessary, has increased the number of positions on the staff to accommodate the proposed increase in the number of stations; and

(2) The water treatment system of the facility is sufficient to ensure the availability of water that is safe for the proposed increase in the number of stations; and

(b) A fee of ~~[$160.]~~ ***$250.***

3. If a facility submits an application pursuant to the provisions of this section, the Bureau may, before considering the application, conduct an inspection of the facility to determine compliance with those provisions.

4. If the Bureau approves an application pursuant to the provisions of this section, the facility shall, not later than 21 days after commencing the use of the stations for which the application was approved, submit to the Bureau a written report concerning the chemical analysis and bacteriologic cultures of the product water of the stations. The written report must be prepared and submitted in accordance with the provisions of ~~[sections 3.2.1 and 3.2.2]~~ ***the most recently published edition*** of the *American National Standard,* ~~[Hemodialysis Systems, March 1992 edition,]~~ ***Water Treatment Equipment for Hemodialysis Applications,*** which is hereby adopted by reference. A copy of the publication may be obtained from the Association for the Advancement of Medical Instrumentation, 1110 North Glebe Road, Suite 220, Arlington, Virginia 22201, for the price of ~~[$50]~~ ***$45*** for members and ~~[$100]~~ ***$90*** for nonmembers.

Sec. 2. NAC 449.525 is hereby amended to read as follows:

449.525 1. The design for the water treatment system of a facility must be:

(a) Based on considerations of the source of water for the facility; and

(b) Prepared by a person who, as determined by the Bureau, has obtained education, training or experience in the design of dialysis systems.

2. If a facility does not obtain water from a public water system, any water used by the facility for medical treatment must be subjected to a bacteriological analysis conducted by the

appropriate health authority or by a commercial laboratory that is certified by the Health Division. An analysis must be conducted pursuant to the provisions of this subsection at least once every 3 months.

3. The area in which the water treatment system of a facility is located must be of sufficient size to allow for the maintenance, testing and repair of the equipment. If any dialysate is mixed in the area, the area must be of sufficient size to house and allow for the mixing of the dialysate and for the maintenance, testing and repair of any equipment used to mix the dialysate.

4. Each component of the water treatment system of a facility must be arranged and maintained in such a manner as to ensure that the amount of bacterial and chemical contaminants in the product water does not exceed the standards for hemodialysis water quality ~~[specified in section 3.2.1,]~~ relating to hemodialysis systems ~~[, and section 3.2.2, relating to]~~ ***and*** maximum level of chemical contaminants ~~[, of]~~ ***set forth in*** the *American National Standard,* ~~[Hemodialysis Systems,]~~ ***Water Treatment Equipment for Hemodialysis Applications,*** adopted by reference pursuant to the provisions of NAC 449.520.

5. Each facility shall prepare and comply with a written policy concerning the operation of the water treatment system of the facility. The written policy must include guidelines for the operation of each component of the water treatment system. The facility shall:

(a) Ensure that each person who operates those components is aware of the guidelines and operates those components in accordance with those guidelines; and

(b) Establish and maintain in the area in which those components are located written procedures describing the actions to be taken if the guidelines are not complied with.

6. Except as otherwise provided in this subsection, the water treatment system of a facility must be equipped with reverse osmosis membranes or deionization tanks and not less than two

carbon tanks arranged in series. If the source of water for the water treatment system is obtained from a private supply that does not use chlorine or chloramine, the water treatment system must be equipped with reverse osmosis membranes or deionization tanks and not less than one carbon tank.

7. If the water treatment system of a facility is equipped with reverse osmosis membranes, the membranes must satisfy the requirements ~~[set forth in section 3.2.3.5,]~~ relating to reverse osmosis ~~[, of]~~ ***set forth in*** the *American National Standard,* ~~[Hemodialysis Systems,]~~ ***Water Treatment Equipment for Hemodialysis Applications,*** adopted by reference pursuant to the provisions of NAC 449.520.

8. If the water treatment system of a facility is equipped with a deionization system, the system must satisfy the requirements ~~[set forth in section 3.2.3.3,]~~ relating to regenerated or reconstituted devices ~~[, and section 3.2.3.4, relating to deionization, of]~~ ***and deionization set forth in*** the *American National Standard,* ~~[Hemodialysis Systems,]~~ ***Water Treatment Equipment for Hemodialysis Applications,*** adopted by reference pursuant to the provisions of NAC 449.520.

9. Each carbon tank that is used in the water treatment system of the facility must:

(a) Contain acid-washed 30-mesh or smaller carbon placed in series with a minimum empty bed contact time of 3 minutes for each tank or bank of tanks; and

(b) Include a testing port that is located between the tanks or bank of tanks. The facility shall, at least once each day before providing treatment to any patient of the facility, test water from the port to determine the amount of chlorine and chloramine in the water. The initial test each treatment day for chlorine and chloramine must be conducted not less than 15 minutes after the water treatment system is started for that day.

10. If the results of a test conducted pursuant to the provisions of subsection 9 indicate the presence of more than 0.5 parts per million of chlorine or 0.1 parts per million of chloramine in the water that is obtained from the port between the initial tank and the final tank of the water treatment system, the facility shall replace the initial tank and conduct a test of the water from the final exit of the water treatment system. If the results of that test indicate the presence of chlorine or chloramine in an amount that is greater than the requirements specified in this subsection, the facility shall immediately terminate any dialysis treatment provided to a patient of the facility and notify the medical director of the facility of the results of the test.

11. If a facility uses a water softener in the water treatment system of the facility, the water softener must have the capacity to treat a sufficient amount of water to supply the facility for the entire treatment day.

12. If a facility uses a cartridge filter in the water treatment system of the facility, the cartridge filter must be made of material that does not leach surfactants, formaldehyde or other material that was used to manufacture the material.

13. If a facility uses a cartridge filter housing during disinfectant procedures, the housing must include a mechanism to clear the lower portion of the housing of the disinfecting agents. Each cartridge filter housing must be opaque.

14. The water treatment system of the facility must be:

(a) Continuously monitored during the treatment of a patient of the facility; and

(b) Protected by audible and visual alarms that are capable of being seen and heard in the dialysis treatment area if the quality of the water used in the water treatment system falls below the standards established by the facility for the water treatment system or the manufacturer of the water treatment system.

15. If the deionization tanks of the water treatment system of a facility do not follow a reverse osmosis system, standards for the rate of rejection of the membranes must ensure that the lowest rate accepted will provide product water in compliance with ~~[section 3.2.2, relating to]~~ ***the*** maximum level of chemical contaminants ~~[, of]~~ ***set forth in*** the *American National Standard,* ~~[Hemodialysis Systems,]~~ ***Water Treatment Equipment for Hemodialysis Applications,*** adopted by reference pursuant to the provisions of NAC 449.520.

16. Each facility shall maintain a written record of the operation of the water treatment system for each treatment day. The written record must include the guidelines established by the facility for operating each component of the system and any action taken during that day if the operation of a component was not within the guidelines established by the facility for that component.

Sec. 3. NAC 449.5255 is hereby amended to read as follows:

449.5255 1. Except as otherwise provided in this section, each facility shall, at least once every 6 months, conduct a chemical test of a sample of the product water of the water treatment system of the facility. The results of any test conducted pursuant to the provisions of this section must indicate that the quality of the product water satisfies the requirements ~~[set forth in section 3.2.2,]~~ relating to maximum level of chemical contaminants ~~[, of]~~ ***set forth in*** the *American National Standard,* ~~[Hemodialysis Systems,]~~ ***Water Treatment Equipment for Hemodialysis Applications,*** adopted by reference pursuant to the provisions of NAC 449.520.

2. A facility shall conduct a chemical test pursuant to the provisions of this section if substantial changes are made to the water treatment system or if the percent of rejection of a reverse osmosis system decreases 5 percent or more from the percent of rejection measured at the time the water sample for the preceding chemical test was taken. If a facility uses a water

treatment system that is portable, the facility shall, at least once each year, conduct a chemical test of the product water in accordance with the provisions of this section.

3. The records maintained by a facility concerning the operation of the facility must include:

(a) The results of each test conducted pursuant to the provisions of this section and NAC 449.525 and 449.526; and

(b) Evidence satisfactory to the Bureau that the medical director of the facility reviewed the results of those tests and required corrective action to be taken if indicated by those results.

Sec. 4. NAC 449.526 is hereby amended to read as follows:

449.526 1. Each facility shall, at least once each month or immediately after any repair or change is made to the water product treatment system of the facility, conduct a microbiological test of the product water. The results of any test conducted pursuant to the provisions of this section must indicate that the quality of the product water satisfies the requirements ~~[specified in section 3.2.1,]~~ relating to hemodialysis systems ~~[, of]~~ ***set forth in*** the *American National Standard,* ~~[Hemodialysis Systems,]~~ ***Water Treatment Equipment for Hemodialysis Applications,*** adopted by reference pursuant to the provisions of NAC 449.520.

2. Sample sites selected by the facility to conduct the test must include the beginning of the distribution piping, the product water in the reuse room of the facility and the end of the distribution piping. If the results of the test do not satisfy the requirements specified in subsection 1, the facility shall immediately disinfect and reculture the water treatment system. If, after the water treatment system is disinfected and recultured, the results of the test do not satisfy those requirements, the facility shall determine the source of the contamination by immediately reculturing:

(a) The sample sites;

(b) Each patient station of the facility;

(c) Each tank of the water treatment system that is used to store water;

(d) All water that is used to mix dialysate; and

(e) The product water obtained from the final component of the water treatment system.

3. A calibrated loop must not be used to conduct a test pursuant to the provisions of this section. As used in this subsection, "calibrated loop" means a mechanism that is used to:

(a) Draw a sample of water from the water treatment system of a facility; and

(b) Conduct a test of that water for the presence of chemicals, bacteria or other impurities.

Sec. 5. NAC 449.5265 is hereby amended to read as follows:

449.5265 1. If a facility reuses any hemodialyzer in providing treatment to a patient of the facility, the facility shall:

(a) Ensure that the reuse of the hemodialyzer is conducted in accordance with the provisions of the *American National Standard,* ~~[~~Hemodialysis Systems,~~]~~ ***Water Treatment Equipment for Hemodialysis Applications,*** adopted by reference pursuant to the provisions of NAC 449.520.

(b) Ensure that each transducer protector used during the treatment is:

(1) Replaced, if it becomes wet during the treatment; and

(2) Used only for one treatment.

(c) Ensure that, in any area of the facility in which the reuse occurs, the supply of water in that area incorporates a mechanism to prevent any chemical agents from flowing into the water distribution system of the facility.

(d) Ensure that any ventilation system installed in an area specified in paragraph (c):

(1) Is connected to an exhaust system that:

(I) Leads to the outside of the building in which the room is located; and

(II) Is separate from the exhaust system of the building;

(2) Has an exhaust fan that is located at the discharge end of the ventilation system;

(3) Has a system of exhaust ducts that is constructed of material that is noncombustible and resistant to corrosion; and

(4) Has an exhaust outlet that is located above the level of the roof of the building to which the exhaust outlet is attached , and ~~[,]~~ if more than one exhaust outlet is installed, the facility shall ensure that each of those outlets is arranged in such a manner as to minimize any recirculation of exhaust air into the building.

(e) Adopt and comply with a policy that sets forth the criteria for reuse, including the number of reuses allowed by the facility.

(f) Ensure that access to an area of the facility specified in paragraph (c) is restricted to persons who are authorized by the facility to enter that area.

(g) Before providing treatment to the patient:

(1) Consider and address the health and safety of the patient if he is sensitive to disinfectant solution residuals;

(2) Provide to the patient information regarding the policy of reuse for the facility and the opportunity to submit and receive a response to questions concerning the reuse; and

(3) Obtain written consent for the reuse from the patient or legal representative of the patient.

2. A facility shall not transport any dialyzer that has been used in the treatment of a patient of the facility or allow a person to transport that dialyzer for reprocessing to a location that is off the premises of the facility unless the facility:

(a) Requires the use of automated equipment at that location to reprocess the dialyzer;

(b) Remains responsible for the entire process of reuse;

(c) Adopts and complies with a policy which ensures that the transfer and transportation of any used or reprocessed dialyzer to and from the location does not increase the contamination of the dialyzer, the environment or any member of the staff of the facility; and

(d) Allows an employee of the Bureau to enter the off-site reprocessing site as part of any inspection of the facility conducted by the Bureau.

Sec. 6. NAC 449.5415 is hereby amended to read as follows:

449.5415 1. Each facility shall adopt a written procedure to be followed by each patient and member of the staff of the facility if any emergency occurs at the facility, including, without limitation, any fire, equipment failure, power outage, medical emergency or natural disaster that may threaten the health or safety of any patient or member of the staff of the facility or any member of the general public.

2. Each facility shall prepare a plan for obtaining emergency medical services that are available for use by the facility.

3. Each facility shall employ personnel who are qualified to operate emergency equipment at the facility and to provide emergency care at the facility. The personnel must be available to operate the emergency equipment and provide emergency care during each period in which treatment is provided to a patient of the facility. A charge nurse who is qualified to provide basic cardiopulmonary life support must be present at the facility and available in the treatment area during any period in which a patient of the facility is present in that area. Each member of the clinical staff of the facility must maintain current certification and competency in basic cardiopulmonary life support.

4. Each facility shall enter into an agreement with at least one hospital that provides acute dialysis service, inpatient care and other hospital services to the patients of the facility. The agreement must include:

(a) Documentation from the hospital indicating that the patients of the facility will be accepted and treated during any emergency that occurs at the facility; and

(b) Reasonable assurances that:

(1) The transfer or referral of a patient will occur between the hospital and the facility if the transfer or referral is determined to be medically appropriate by the attending physician of the patient;

(2) The exchange of medical and other information necessary or useful in the care and treatment of the patient transferred will occur within 1 working day after the transfer or referral of the patient; and

(3) All personal property belonging to and transferred with the patient will be accounted for and protected from theft, loss or damage.

5. Each facility shall establish and comply with a written plan to protect each patient of the facility if a fire occurs at the facility. The written plan must include:

(a) Provisions concerning the evacuation of each person from each building of the facility during a fire; and

(b) A diagram that specifies the routes to be taken to evacuate each of those buildings. A copy of each diagram prepared pursuant to the provisions of this paragraph must be posted in a conspicuous place in the building for which the diagram is prepared.

6. Each facility shall, not less than once each quarter, conduct a fire drill at the facility. The facility shall rotate the occurrence of the fire drills to ensure that each patient shift participates in

a fire drill at least once each year. Each fire drill must include the use of alarms and equipment and a discussion with the patients, visitors, employees and members of the staff of the facility concerning evacuation from each building of the facility. After conducting a fire drill, the facility shall prepare and maintain a written report concerning the fire drill. The written report must include evidence that the members of the staff and the patients of the facility participated in the fire drill.

7. Each facility shall ensure that each member of the staff of the facility is familiar with the location of all equipment that is used to suppress fires at the facility. The equipment must be located in such a manner that a person is not required to travel more than 75 feet from any location in the facility to reach the equipment.

8. Each facility shall prepare and comply with a written plan concerning preparation for any disaster that may occur at the facility. The plan must:

(a) Be based on an assessment of the probability and type of disaster in each region and the local resources available to the facility;

(b) Include procedures that are designed to:

(1) Minimize the harm to the patients and members of the staff of the facility; and

(2) Ensure the safe operation of the facility during a disaster; and

(c) Include provisions concerning:

(1) The assignment of responsibilities for each member of the staff of the facility during a disaster, including the assignment of direction and control of the facility;

(2) The maintenance of equipment used for communication during a disaster;

(3) The use of warning systems; and

(4) Evacuation from and closure of the facility because of a disaster.

9. Each facility shall adopt written procedures to ensure that water is available to the essential areas of the facility if there is an interruption in the facility's normal supply of water.

Sec. 7. NAC 449.571 is hereby amended to read as follows:

449.571 1. Each program for training a dialysis technician provided by a facility must consist of a written curriculum that specifies the objectives for each portion of the course.

2. The written curriculum must include at least the following subjects:

(a) Introduction to dialytic therapies, including:

(1) The history of dialysis;

(2) Definitions and terminology;

(3) Communication skills;

(4) Ethics and confidentiality;

(5) The multidisciplinary process;

(6) The roles of the members of an interdisciplinary team established pursuant to the provisions of NAC 449.541; and

(7) Information concerning renal organizations and resources;

(b) The principles of hemodialysis, including:

(1) The principles of dialysis;

(2) Access to the circulatory system; and

(3) Anticoagulation, local anesthetics and normal saline;

(c) Understanding a person who suffers from kidney failure, including:

(1) Basic renal anatomy, physiology and pathophysiology;

(2) The effect of renal failure on the systems of the body;

(3) The symptoms and findings related to the uremic state;

(4) The modes of renal replacement therapy, including kidney transplantation;

(5) Basic renal nutrition;

(6) Basic psychosocial aspects of end-stage renal disease;

(7) The medications commonly administered to a patient who is diagnosed with end-stage renal disease, including the manner of administering and the effects of those medications;

(8) Confidentiality of the personal and clinical records of a patient of a facility;

(9) Professional conduct;

(10) The rights and responsibilities of a patient of a facility; and

(11) Rehabilitation of a patient of a facility;

(d) Procedures relating to dialysis, including:

(1) Using aseptic techniques;

(2) The technical aspects of dialysis, operation and monitoring of equipment, and the commencement and termination of dialysis;

(3) Delivering dialysis treatment adequately and circumstances that may result from inadequate treatment;

(4) Observing and reporting the reaction of a patient to treatment;

(5) Monitoring glucose and hemoglobin or hematocrit monitoring;

(6) Emergency procedures and responses, including cardiopulmonary resuscitation, the management of an air embolism, and the proper response to line separation and hemolysis;

(7) External and internal disasters, fire, natural disasters and preparation for an emergency; and

(8) Safety, control of quality and improvement of quality;

(e) Information concerning devices used for hemodialysis, including:

(1) The theory and practice of conventional, high efficiency and high flux dialysis;

(2) Dialysate composition, options, indications, complications and safety;

(3) Monitoring and safety; and

(4) Disinfecting equipment;

(f) The treatment of water, including:

(1) Standards for water treatment used for dialysis as described in the *American National Standard,* ~~[~~Hemodialysis Systems,~~]~~ ***Water Treatment Equipment for Hemodialysis Applications,*** adopted by reference pursuant to the provisions of NAC 449.520;

(2) Systems and devices;

(3) Monitoring; and

(4) The risk of harm to a patient who uses untreated water;

(g) If the facility reuses water, information concerning the reprocessing of water, including:

(1) Principles of reuse;

(2) Safety, control of quality, standard precautions and water treatment; and

(3) Standards for reuse as described in the *American National Standard,* ~~[~~Hemodialysis Systems,~~]~~ ***Water Treatment Equipment for Hemodialysis Applications,*** adopted by reference pursuant to the provisions of NAC 449.520;

(h) Providing instruction for a patient of a facility, including:

(1) The role of the technician in supporting the goals of the patient concerning education; and

(2) The principles of adult education;

(i) Safety and the control of infection, including:

(1) The risk of harm to a patient from nosocomial infections and from accidents and errors in providing treatment;

(2) Standard precautions, aseptic and sterile techniques, and proper handling of a specimen;

(3) Basic bacteriology and epidemiology;

(4) The risk of harm to an employee of a facility resulting from exposure to blood and chemicals; and

(5) Electrical, fire, disaster and environmental safety and hazardous substances; and

(j) The assurance and improvement of quality, including:

(1) The role of the dialysis technician in activities concerning the assurance of quality;

(2) The principles of the assurance and improvement of quality; and

(3) The importance of the assurance of quality to ensure that safe dialysis treatments are provided to each patient of the facility.

3. In addition to the requirements set forth in subsection 2, if a dialysis technician intends to assist in providing training or treatment to a patient of the facility who receives peritoneal dialysis, the program of training for the dialysis technician must include the following subjects:

(a) The principles of peritoneal dialysis;

(b) Sterile techniques;

(c) The systems for the delivery of peritoneal dialysis;

(d) The symptoms of peritonitis; and

(e) The complications of peritoneal dialysis.

4. In addition to the requirements set forth in subsection 2, if a dialysis technician intends to cannulate a dialysis access during the treatment of a patient of the facility or administer normal

saline, heparin or lidocaine to that patient, the program of training for the dialysis technician must include the following subjects:

(a) Access to circulation, including:

(1) Fistula: creation, development, placement of needles and prevention of complications;

(2) Grafts: materials used, creation, placement of needles and prevention of complications; and

(3) Symptoms to report;

(b) Safe administration of medications, including:

(1) Identifying the patient;

(2) Ensuring the proper administration of medication;

(3) Measuring the correct dose;

(4) Ascertaining the correct route to administer the dose; and

(5) Ensuring the correct time to administer the dose;

(c) Administration of normal saline, including:

(1) The reasons for administration;

(2) Potential complications;

(3) The limits of administration; and

(4) Information to report and record;

(d) Administration of heparin, including:

(1) The reasons for administration;

(2) The methods of administration;

(3) The preparation of an ordered dose;

(4) Potential complications; and

(5) Information to report and record; and

(e) Administration of lidocaine, including:

(1) The reasons for administration;

(2) The method of administration;

(3) The preparation of an ordered dose;

(4) Potential complications and risks; and

(5) Information to report and record.

5. The instructor of a course of training provided to a dialysis technician shall:

(a) Maintain a roster of attendance for each dialysis technician enrolled in the course; and

(b) At least once each week during the course, evaluate each dialysis technician enrolled in the course to determine the progress of the dialysis technician in completing the course.

6. Except as otherwise provided in subsection 7, each dialysis technician specified in subsection 5 must complete a written examination. The examination must include each of the subjects specified in subsections 2 and 3. If the dialysis technician intends to cannulate a dialysis access during the treatment of a patient of the facility or administer normal saline, heparin or lidocaine to that patient, the examination must include the subjects specified in subsection 4. To pass the written examination, the dialysis technician must achieve a score of not less than 80 percent on each of the subjects required to be included in the written examination pursuant to the provisions of this subsection.

7. The provisions of subsection 6 do not apply to a dialysis technician who is certified as a dialysis technician by an organization that is approved by the Bureau.

NOTICE OF ADOPTION OF PROPOSED REGULATION
LCB File No. R075-04

The Health Division of the Department of Human Resources adopted regulations assigned LCB File No. R075-04 which pertain to chapter 449 of the Nevada Administrative Code on June 25, 2004.

Notice date: 5/25/2004
Hearing date: 6/25/2004
Date of adoption by agency: 6/25/2004
Filing date: 8/5/2004

INFORMATIONAL STATEMENT

1. DESCRIPTION OF HOW PUBLIC COMMENT WAS SOLICITED, SUMMARY OF PUBLIC RESPONSE, AND AN EXPLANATION OF HOW OTHER INTERESTED PERSONS MAY OBTAIN A COPY OF THE SUMMARY.

A Small Business Impact Questionnaire was mailed to the ESRD facilities on February 27, 2004. Attachment A is the Small Business Impact Statement Questionnaire. Attachment B is a copy of the small business impact summary.

Notice of public workshops held on March 29, 2004, in Las Vegas and on April 1, 2004, in Reno was published in the Las Vegas Review Journal and Reno Gazette Journal on March 10, 2004. Notices of public workshops, and proposed regulations were mailed to all county libraries in Nevada, ESRD facilities, and interested parties on February 27, 2004. The small business impact summary was available at both workshops.

Larry Farr, City of Reno Fire Department, stated that he was overall pleased with the uniform codes for plan review.

Notice of public hearing regarding the Board's intent to adopt amendments was published in the Las Vegas Review Journal and Reno Gazette Journal on May 25, 2004. Notices of public hearing, and proposed regulations were mailed to all county libraries in Nevada, ESRD facilities and interested parties on May 25, 2004. The notice of public hearing was mailed to the Clark County Health District and the Washoe County District Health Department on May 25, 2004.

Copies of the workshop minutes and Board of Health hearing minutes may be obtained by calling the Bureau of Licensure and Certification at (775) 687-4475.

2. THE NUMBER OF PERSONS WHO:

(A) ATTENDED THE HEARING;

Approximately 69 people attended the June 25, 2004, Board of Health hearing.

(B) TESTIFIED AT EACH HEARING; AND

No one in attendance testified on Facilities for Treatment of Irreversible Renal Disease regulations.

(C) SUBMITTED TO THE AGENCY WRITTEN STATEMENTS.

No written statements were provided to the agency.

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

Comment was solicited from affected or potentially affected businesses by mailing appropriate facilities and all interested parties the proposed regulations, a small business impact questionnaire, a copy of the small business impact summary, and the notices for the workshops and Board of Health hearings. Copies of the workshop minutes and Board of Health hearing minutes may be obtained by calling the Bureau of Licensure and Certification at (775) 687-4475.

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.

No testimony was received in opposition to the proposed regulation or which suggested changes to the proposed regulation.

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

Anticipated effects on the business which NAC 449 regulates.

Adverse: The plan review will have an associated fee as determined by the entity conducting the review on behalf of the state.

Beneficial: Regulations addressing plan review and disaster planning will be more consistent throughout all facility types.

Anticipated effects on the public:

Adverse: None

Beneficial: The proposed regulations will require the majority of facilities to have a plan review ensuring a safe environment for the public.

(B) BOTH IMMEDIATE AND LONG TERM EFFECTS.

Anticipated effects on the business which NAC 449 regulates.

Immediate: None

Long-term: Regulations addressing plan review and disaster planning will be more consistent throughout all facility types.

Anticipated effects on the public:

Immediate: None

Long-term: The proposed regulations will require the majority of facilities to have a plan review thus ensuring a safe environment for the public.

6. THE ESTIMATED COST TO THE AGENCY FOR ENFORCEMENT OF THE PROPOSED REGULATION.

There will be additional staff time to register plans for the facilities that will now be required to have a plan review. The plan review will have an associated fee as determined by the entity conducting the review on behalf of the state. No other fee increases are associated with the proposed regulations.

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.

There is no duplication or overlap of other state or local government agency's regulations.

8. IF THE REGULATION INCLUDES PROVISION WHICH ARE MORE STRINGENT THAN A FEDERAL REGULATION WHICH REGULATES THE SAME ACTIVITY, A SUMMARY OF SUCH PROVISION.

The proposed regulations do not overlap or duplicate federal regulations. The regulations do not have a counterpart in the code of federal regulations.

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.

None.

SMALL BUSINESS IMPACT STATEMENT

Plan Review and Dietary Services

Background:

The purpose of the proposed revised regulations for plan review is to require a review of architectural plans for the majority of facility types.

The construction standards regulations were revised to adopt by reference the National Fire Protection Association's (NFPA) 101 Life Safety Code, and the NFPA 99 Health Facilities Standards and the American Institute of Architects Guidelines for Design and Construction of Hospitals and Health Care Facilities throughout all applicable facility types. The revisions included changing the "Uniform Building Code" to local building codes due to changes being made on a national level from the "Uniform Building Code" to the International Codes or the National Fire Protection 5000 codes. It is the intent of the Bureau of Licensure and Certification (BLC) to eliminate a conflict between the state requirements and the local requirements in the area of the building codes.

The regulations addressing the dietary personnel of hospitals were revised to allow the director of the dietetic services department to have professional qualifications in the area of professional chef, hotel-restaurant management, or is certified at minimum as a dietary manager and has additional work experience with medical-therapeutic diets.

The regulations addressing the requirement for a food establishment permit issued by the Bureau of Health Protection Services (BHPS), in Intermediate Care Facilities, Facilities for the Treatment of Alcohol and Drug Abuse, Modified Medical Detoxification Facilities were revised to require facilities with more than 10 clients/residents to have an inspection and permit.

Interested individuals can obtain a copy of the information packet, including the Small Business Impact Questionnaire, sent to all licensed facilities, from Shirley Rains, Administrative Assistant III, Bureau of Licensure and Certification, 1550 East College Parkway, Suite 158, Carson City, Nevada 89703

1. A description of the manner in which comment was solicited from affected small businesses, a summary of their response and an explanation of the manner in which other interested persons may obtain a copy of the summary.

Pursuant to NRS 233B.0608 (2) (a), the BLC has requested input from operators of the following facility types:

Obstetric Care
Facilities for the Treatment of drug and Alcohol Abuse
Facilities for Treatment of Irreversible Renal Disease
Hospitals
Independent Centers for Emergency Medical Care

Mobile Units
Facilities for Modified Medical Detoxification
Facilities for the Care of Adults During the Day
Surgical Centers for Ambulatory Patients
Intermediate Care Facilities

A Small Business Impact Statement Questionnaire was send to the facilities in the table above along with written correspondence detailing the proposed amendments, including a copy of the proposed regulations, on February 27, 2004. The questions on the questionnaire were:

2) Will a specific regulation have an adverse economic effect upon your business?
3) Will the regulation(s) have any beneficial effect upon your business?
4) Do you anticipate any indirect adverse effects upon your business?
5) Do you anticipate any indirect beneficial effects upon your business?

Facility Type	Number of Responses
Ambulatory Surgery Center	3
Hospital	4
End Stage Renal Dialysis Center	1

Saint Rose Dominican Hospitals responded by indicating the regulations will have an adverse economic effect upon our business. A comment was included that stated they feel plan review should be conducted early in the process for identification of any potential oversight in the specifications before the licensing inspection is conducted.

This respondent states that NAC 449.3156(1) (d) should read …the use of the physical space has not changed in such a way to not comply with the Guidelines for Design and Construction of Hospitals and Health Care Facilities or cause serious injury, serious harm or impairment to public health and welfare.

Additionally, this respondent stated that the regulations at NAC 449.3385(2) will have a beneficial effect upon the hospital because the changes in the regulation will make this position much easier to fill, and still contains the clinical dietetic advantages.

2. The estimated economic effect of the proposed regulation on the small business which it is to regulate including without limitation both adverse and beneficial effects and both direct and indirect effects.

There will be an added economic effect to those facilities previously not required to submit architectural plans for review, however, the benefit in identifying potential non-compliance at a point where changes must be made to plans, rather than a constructed building, balance the costs of the plan review.

The proposed revisions to the dietary personnel requirements will not have additional economic effect on a facility.

The regulations revising the requirement for facilities with more than 10 clients/residents to have an inspection and permit issued by the Bureau of Health Protection Services (BHPS), in Intermediate Care Facilities, Facilities for the Treatment of Alcohol and Drug Abuse, Modified Medical Detoxification Facilities provides a cost saving in these facilities not being required to purchase commercial grade kitchen equipment to obtain a food establishment permit in a facility with less than 10 clients.

3. A description of the methods that BLC considered to reduce the impact of the proposed regulation on small businesses and statement regarding whether the agency actually used those methods.

The BLC considered the impact of facilities in certain counties with populations over 50,000 of the potential of having multiple building codes adopted. The BLC revised the construction standards regarding building codes to eliminate duplicity and possible contradictory requirements.

4. The estimated cost to the agency for enforcement of the proposed regulation.

The estimated cost to the agency for enforcement of the proposed amendments to NAC 449.016 and 449.0168 is negligible.

5. Total amount BLC expects to collect from any fees and the manner in which the money will be used.

The revisions to the plan review and dietary services regulations will not increase licensing fees.

6. An explanation of why any duplicative or more stringent provisions than federal, state or local standards regulating the same activity are necessary.

No duplication or more stringent provision are either created or already in existence.