

**ADOPTED REGULATION OF THE  
STATE BOARD OF HEALTH**

**LCB File No. R053-02**

Effective July 24, 2002

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

AUTHORITY: §§1-11, NRS 449.038.

**Section 1.** Chapter 449 of NAC is hereby amended by adding thereto a new section to read as follows:

*“SAMHSA” means the Substance Abuse and Mental Health Services Administration of the United States Department of Health and Human Services.*

**Sec. 2.** NAC 449.154 is hereby amended to read as follows:

449.154 As used in NAC 449.154 to 449.15485, inclusive, *and section 1 of this regulation*, unless the context otherwise requires, the words and terms defined in NAC 449.15415 to 449.15435, inclusive, *and section 1 of this regulation* have the meanings ascribed to them in those sections.

**Sec. 3.** NAC 449.1542 is hereby amended to read as follows:

449.1542 “Facility for treatment with narcotics” means any person or any public or private facility that provides a narcotic treatment program described in ~~[21 C.F.R. Part 291.]~~ *42 C.F.R. Part 8.*

**Sec. 4.** NAC 449.1544 is hereby amended to read as follows:

449.1544 The health division is the state authority for the purposes of ~~[21 C.F.R. Part 291.]~~ *42 C.F.R. Part 8.*

**Sec. 5.** NAC 449.15445 is hereby amended to read as follows:

449.15445 1. A person or a public or private facility shall not operate or provide the services of a facility for treatment with narcotics or represent that it operates or provides the services of a facility for treatment with narcotics, unless the person or the public or private facility is:

(a) Licensed by the health division pursuant to NAC 449.154 to 449.15485, inclusive, to operate the facility for treatment with narcotics; and

(b) ~~[Approved by the FDA]~~ *Certified by the SAMHSA* pursuant to ~~[21 C.F.R. Part 291]~~ *42 C.F.R. Part 8* to operate the facility for treatment with narcotics.

2. A person or a public or private facility shall not operate or provide the services of a medication unit or represent that it operates or provides the services of a medication unit, unless the person or the public or private facility is:

(a) Licensed by the health division pursuant to NAC 449.154 to 449.15485, inclusive, to operate the medication unit and the facility for treatment with narcotics that is associated with the medication unit; and

(b) ~~[Approved by the FDA]~~ *Certified by the SAMHSA* pursuant to ~~[21 C.F.R. Part 291]~~ *42 C.F.R. Part 8* to operate the medication unit and the facility for treatment with narcotics that is associated with the medication unit.

**Sec. 6.** NAC 449.1545 is hereby amended to read as follows:

449.1545 1. If a person or a public or private facility wants to operate a facility for treatment with narcotics or a medication unit, the person or the public or private facility must:

(a) File with the ~~[FDA]~~ *SAMHSA* an application for ~~[approval]~~ *certification* pursuant to ~~[21 C.F.R. Part 291;]~~ *42 C.F.R. Part 8;*

(b) File with the bureau an application for a license pursuant to NAC 449.011 and include with the application ~~{any}~~:

*(1) If there is an accreditation body that has been approved pursuant to 42 C.F.R. § 8.3, proof that the applicant has applied for accreditation from such accreditation body; and*

*(2) Any other information requested by the bureau; and*

(c) Demonstrate that the proposed facility for treatment with narcotics or the proposed medication unit is able to comply with the requirements set forth in NAC 449.1548.

2. A person or a public or private facility must file an application for a license for each facility for treatment with narcotics that it wants to operate, whether or not the person or the public or private facility is already licensed to operate one or more other facilities for treatment with narcotics.

3. A person or a public or private facility must file an application for a license for each medication unit that it wants to operate, whether or not the person or the public or private facility is already licensed to operate one or more other medication units.

*4. The health division may make a recommendation to the SAMHSA that an applicant for certification of a facility for treatment with narcotics or a medication unit be certified, if the applicant has:*

*(a) Satisfied all the requirements for licensure by the health division pursuant to NAC 449.154 to 449.15485, inclusive;*

*(b) Submitted all items required pursuant to NAC 449.011; and*

*(c) Provided satisfactory evidence to the health division that the facility is in substantial compliance with the requirements of 42 C.F.R. Part 8.*

**Sec. 7.** NAC 449.15455 is hereby amended to read as follows:

449.15455 1. If an application for a license is filed pursuant to NAC 449.1545, the bureau shall conduct pursuant to NAC 449.0112:

- (a) An investigation; and
- (b) ~~[Except as otherwise provided in NAC 449.1546, a]~~ A prelicensure survey.

2. The investigation and any prelicensure survey conducted by the bureau must include, but are not limited to, an evaluation of whether the proposed facility for treatment with narcotics or the proposed medication unit is able to comply with the requirements set forth in NAC 449.1548.

~~[3.— After completing its investigation and any prelicensure survey, the bureau shall submit to the administrator of the health division, or his designee, a recommendation concerning whether the application for the license should be approved or denied.~~

~~—4.— The administrator of the health division, or his designee, shall approve or deny the application for the license.~~

~~—5.— Not later than 30 days after the decision of the administrator of the health division, or his designee, the bureau shall provide notice of the decision to the person or the public or private facility that filed the application for the license. If the decision is a denial of the application for the license, the notice provided by the bureau must also comply with NAC 449.15475.]~~

**Sec. 8.** NAC 449.1547 is hereby amended to read as follows:

449.1547 1. The health division may suspend or revoke a license issued pursuant to NAC 449.154 to 449.15485, inclusive, or cancel such a license and issue a provisional license based upon any grounds for such action set forth in this chapter or chapter 449 of NRS.

2. The health division shall ~~[consider, without limitation, the seriousness of the violation and the frequency and duration of the violation in determining whether to suspend or revoke a license or cancel a license and issue a provisional license.]~~ *deny an application for a license*

*pursuant to NAC 449.1545 if the SAMHSA denies an application for certification pursuant to 42 C.F.R. Part 8.*

*3. The health division shall suspend or revoke a license issued pursuant to NAC 449.154 to 449.15485, inclusive, if the facility for treatment with narcotics or the medication unit operates without certification from the SAMHSA pursuant to 42 C.F.R. Part 8.*

**Sec. 9.** NAC 449.1548 is hereby amended to read as follows:

449.1548 In addition to all other requirements set forth in NAC 449.154 to 449.15485, inclusive, each facility for treatment with narcotics and each medication unit shall:

1. Have a medical director who has a valid and current license to practice medicine in this state;
2. Employ, contract with or allow a person to act as an alcohol and drug abuse counselor only if the person is certified by the board of examiners for alcohol and drug abuse counselors to be such a counselor;
3. Obtain and maintain with the state board of pharmacy a valid and current registration relating to the use of narcotics;
4. Be in full compliance with all applicable provisions of ~~[21 C.F.R. Parts 291 and 1300 to 1316, inclusive.]~~ *42 C.F.R. Part 8*, all other applicable federal laws and regulations and all other requirements of the ~~[FDA]~~ *SAMHSA* and *the* DEA;
5. Be in full compliance with all applicable provisions of chapters 449 and 453 of NRS and in substantial compliance with all applicable provisions of this chapter and chapter 453 of NAC;
6. Maintain records and documentation of treatment pursuant to NRS 453.690;
7. Provide the health division and the state board of pharmacy with access to all records and documentation relating to the purchase, distribution and use of narcotics;

8. Comply with the rules of confidentiality and privilege set forth in NRS 453.720;
9. Develop and maintain a system to ensure that prospective and existing clients are not receiving narcotics from any other facility for treatment with narcotics or any other medication unit; and
10. Comply with all applicable local laws and regulations, including, but not limited to, zoning laws and regulations.

**Sec. 10.** NAC 449.15485 is hereby amended to read as follows:

449.15485 1. The operation of a facility for treatment with narcotics or a medication unit is subject to continuing review by the health division.

2. The health division shall investigate all complaints against a facility for treatment with narcotics or a medication unit directly or in conjunction with other federal, state or local governmental agencies, including, but not limited to, the ~~FDA,~~ **SAMHSA**, the DEA, the state board of pharmacy or the health division.

**Sec. 11.** NAC 449.15425, 449.1546, 449.15465 and 449.15475 are hereby repealed.

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### TEXT OF REPEALED SECTIONS

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**449.15425 “FDA” defined.** “FDA” means the Food and Drug Administration of the United States Department of Health and Human Services.

**449.1546 Accreditation may be accepted in lieu of precicensure survey or other site survey.** If a facility for treatment with narcotics or a medication unit is accredited by the health division, the health division may accept that accreditation in lieu of conducting a precicensure survey pursuant to NAC 449.15455 or any other site survey, if the health division receives certification that the facility or the medication unit is accredited and in compliance with all applicable provisions of 21 C.F.R. Parts 291 and 1300 to 1316, inclusive.

**449.15465 Letter of approval; withdrawal for noncompliance with regulations.**

1. If an application for a license is approved by the administrator of the health division, or his designee, pursuant to NAC 449.154 to 449.15485, inclusive, the health division shall issue a letter of approval to the FDA informing the FDA that the person or the public or private facility holding the license is approved to operate the facility for treatment with narcotics or the medication unit that is identified in the license.

2. A letter of approval issued by the health division to the FDA may be withdrawn if the health division determines that the facility for treatment with narcotics or the medication unit is not in compliance with any applicable provision of a federal, state or local law or regulation.

NAC 449.15475 is hereby amended to read as follows:

**449.15475 Notice of denial of application or other disciplinary action; appeals.**

1. The health division or the bureau, as appropriate, shall provide notice of the denial of an application for a license, the withdrawal of a letter of approval or the imposition of any other disciplinary action in the manner set forth in NAC 439.300 to 439.395, inclusive.

2. A person or a public or private facility that is aggrieved by the denial of an application for a license, the withdrawal of a letter of approval or the imposition of any other disciplinary action may appeal that action in the manner set forth in NAC 439.300 to 439.395, inclusive.

**NOTICE OF ADOPTION OF PROPOSED REGULATION  
LCB File No. R053-02**

The Bureau of Licensure and Certification of the Health Division of the Department of Human Resources adopted regulations assigned LCB File No. R053-02 which pertain to facilities for treatment with narcotics (chapter 449 of the Nevada Administrative Code) on June 14, 2002.

**Notice date:** May 14, 2002  
**Hearing date:** June 14, 2002

**Date of adoption by agency:** June 14, 2002  
**Filing date:** July 24, 2002

**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 Facilities for Treatment with Narcotics; Medication Units on April 1, 2002. Attached is a copy of the Small Business Impact Summary.

Notice of public workshops held on April 24, 2002, in Las Vegas and April 25, 2002, in Reno was published in the Las Vegas Review Journal and Reno Gazette Journal on or before April 8, 2002. Notices of public workshops, and proposed regulations were mailed to all county libraries in Nevada, Facilities for Treatment with Narcotics; Medication Units, and interested parties on April 1, 2002. The small business impact summary was available at both workshops.

Notice of public hearing regarding the Board's intent to adopt amendments was published in the Las Vegas Review Journal, Reno Gazette Journal on or before May 15, 2002. Notices of public hearing, proposed regulations and the small business impact summary was mailed to all county libraries in Nevada, Clark County Health District, Washoe County Health District, Facilities for Treatment with Narcotics; Medication Units, and interested parties on May 9, 2002.

**2. THE NUMBER OF PERSONS WHO:**

**(A) ATTENDED THE HEARING;**

Approximately 32 people attended the June 14, 2002, Board of Health hearing.

**(B) TESTIFIED AT EACH HEARING; AND**

No one in attendance testified on Facilities for Treatment with Narcotics.

**(C) SUBMITTED TO THE AGENCY WRITTEN STATEMENTS.**

No written statements were provided at the hearing.



**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 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.**

None.

**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.**

None, this amendment will make Nevada law consistent with changes in federal law.

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

There will be no economic impact on the Bureau of Licensure and Certification due to the fact that surveys are already being conducted in these facilities and licensing fees are already in place.

**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. Additionally, there is no overlap or duplication of a federal 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.**

None.

**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.**

There are no new fees or fee increases.

**SMALL BUSINESS IMPACT STATEMENT**  
(Nevada Revised Statutes 233B.0608)

PROPOSED CHANGES TO THE REGULATIONS for Facilities for Treatment with Narcotics.

Background

The proposed changes will update the existing Nevada Administrative Code to adopt the new Federal regulations that govern the provision of methadone treatment for heroin addiction. In July of 1999, The Substance Abuse and Mental Health Services Administration (SAMHSA), which serves as the umbrella under which substance abuse and mental health service centers are housed at the United States Department of Health and Human Services, proposed a certification system based on accreditation for all Opioid Treatment Programs (OTPs) also known as narcotic treatment programs or methadone programs. All methadone treatment clinics are now required by Federal Law to obtain accreditation from an accrediting organization approved by SAMHSA. Nevada has 11 treatment clinics, three in the Reno area and eight in the Las Vegas area. In an effort to provide education on regulations to the provider community, the Bureau of Licensure and Certification (BLC) mails or faxes all treatment facilities in Nevada copies of all memorandum's received from the American Association for the Treatment of Opioid Dependence, Inc. or from SAMHSA, regarding the new Federal regulations and technical assistance available to providers. The BLC has determined that the adoption of these regulations should not create an economic or operational impact on licensed facilities because they do not involve a change of fees at the state level. 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." This small business impact statement complies with the requirements of NRS 233B.0609.

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

The proposed changes to the regulations and a small business impact questionnaire were provided to the administrators of all licensed Facilities for Treatment with Narcotics. Seven responses were received. The comments received are summarized below:

1. Four respondents were concerned about the cost of accreditation engendered by the adoption of the new federal requirements and that the increased costs could not be passed on to their clients. Accreditation is a mandatory requirement of the federal government for all clinics that provide treatment with narcotics. Without this accreditation, the clinic cannot operate. Therefore, the incorporation of the federal requirements into the Nevada Administrative Code does not in and of itself, cause the accreditation fees. Additionally, the Centers for Substance Abuse Treatment – Substance Abuse and Mental Health Service Administration (CSAT/SAMHSA) offers a \$1000 accreditation education fund and a deduction of \$3000 per survey for each clinic.

2. Two respondents felt that the inclusion of the federal regulations in the NAC would have a beneficial effect by not requiring the facilities to comply with an additional set of regulations.
3. One respondent felt that providing a regulatory framework for the operation of a treatment program improves the standard of care and that these regulations are reasonable and in no way onerous.
4. One respondent felt that implementing the federal requirements would be positive for both the clinic and the client.
5. Two respondents indicated that there would be no beneficial or adverse effect caused by the proposed changes.

Copies of the summaries of these questionnaires are available from the office of the Bureau of Licensure and Certification 4220 South Maryland Parkway, Building D, Suite 810, Las Vegas, Nevada 89119. (702) 486-6515.

**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.**

The beneficial effect to the facilities by the adoption of the Federal requirements to avoid requiring a facility to comply with two different sets of regulations. The adverse effect is the accreditation fees. However, accreditation is a mandatory requirement of the federal government for all clinics that provide treatment with narcotics. Without this accreditation, the clinic cannot operate. Therefore, the incorporation of the Federal requirements into the Nevada Administrative Code does not cause the accreditation fees. The federal requirements dictate that if a state requires licensure of this facility type within the state, the accrediting body would similarly require state licensure for the federal accreditation process. At this time, the state facilities that are currently licensed by BLC have provisional accreditation by the federal agency for a period of up to three years from the date of application. New facilities seeking state licensure would be licensed by the state, and receive temporary federal accreditation pending their successful federal accreditation survey process.

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

The agency reviewed the suggestions for changes that would lessen the economic impact. Wherever possible, in keeping with existing state laws, these changes have been made.

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

There will be no increased cost to BLC because the proposed changes to the regulations do not require additional survey time.

**5. If the proposed 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 associated fee increase required by the adoption of the proposed changes to the regulations

- 6. If the proposed regulation includes provisions which duplicate or are more stringent than federal, state or local standards regulating the same activity, an explanation of why such duplicative or more stringent provisions are necessary.**

The proposed changes adopt the mandatory federal requirements for facilities for treatment with narcotics and therefore do not force the facility to comply with an additional set of regulations