

**PROPOSED REGULATION OF THE  
STATE BOARD OF HEALTH**

**LCB File No. R053-02**

June 3, 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.

---

---

### TEXT OF REPEALED SECTIONS

---

---

**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.