

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

LCB File No. R229-97

February 2, 1998

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

AUTHORITY: §§2-20, 23 and 24, NRS 449.037 and 449.038; §§21 and 22, NRS 439.150 and 449.050.

Section 1. Chapter 449 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 20, inclusive, of this regulation.

Sec. 2. *“Facility for treatment with narcotics” has the meaning ascribed to it in section 7 of this regulation.*

Sec. 3. *“Medication unit” has the meaning ascribed to it in section 10 of this regulation.*

Sec. 4. *As used in sections 4 to 20, inclusive, of this regulation, unless the context otherwise requires, the words and terms defined in sections 5 to 10, inclusive, of this regulation have the meanings ascribed to them in those sections.*

Sec. 5. *“Bureau of alcohol and drug abuse” means the bureau of alcohol and drug abuse in the rehabilitation division of the department of employment, training and rehabilitation.*

Sec. 6. *“D.E.A.” means the Drug Enforcement Administration of the United States Department of Justice.*

Sec. 7. *“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.*

Sec. 8. *“F.D.A.” means the Food and Drug Administration of the United States*

Department of Health and Human Services.

Sec. 9. *“Medical director” means a physician who is licensed to practice medicine in this state and who is responsible for the administration of all medical services at a facility for treatment with narcotics or a medication unit and for ensuring that the facility or the medication unit complies with all applicable federal, state and local laws and regulations.*

Sec. 10. *“Medication unit” means any person or any public or private facility that:*

- 1. Is established as part of or operates in conjunction with a facility for treatment with narcotics but is separated geographically from the facility for treatment with narcotics;*
- 2. Is authorized to administer or dispense narcotics; and*
- 3. Is authorized pursuant to chapter 652 of NRS to collect samples for drug testing or analysis relating to treatment with narcotics.*

Sec. 11. *The health division is the state authority for the purposes of 21 C.F.R. Part 291.*

Sec. 12. *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 sections 4 to 20, inclusive, of this regulation to operate the facility for treatment with narcotics; and

(b) Approved by the F.D.A. pursuant to 21 C.F.R. Part 291 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 sections 4 to 20, inclusive, of this regulation to operate the medication unit and the facility for treatment with narcotics that is associated with the medication unit; and

(b) Approved by the F.D.A. pursuant to 21 C.F.R. Part 291 to operate the medication unit and the facility for treatment with narcotics that is associated with the medication unit.

Sec. 13. *In addition to all other requirements set forth in sections 4 to 20, inclusive, of this regulation, 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 bureau of alcohol and drug abuse 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 1316, all other applicable federal laws and regulations and all other requirements of the F.D.A. and D.E.A.;*

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 chapters 449 and 453 of NAC;*

6. *Maintain records and documentation of treatment pursuant to NRS 453.690;*

7. *Provide the health division, the state board of pharmacy and the bureau of alcohol and drug abuse 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 registry system that is part of the state registry system established by the bureau of alcohol and drug abuse 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. 14. *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 F.D.A. an application for approval pursuant to 21 C.F.R. Part 291;

(b) File with the bureau an application for a license pursuant to section 2 of LCB File No. R044-97, which was adopted by the state board of health and was filed with the secretary of state on October 30, 1997, and include with the application any other information requested by the bureau; and

(c) Demonstrate that proposed facility for treatment with narcotics or the proposed medication unit is able to comply with the requirements set forth in section 13 of this regulation.

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.

Sec. 15. *1. If an application for a license is filed pursuant to section 14 of this regulation, the bureau shall conduct pursuant to section 3 of LCB File No. R044-97, which was adopted by the state board of health and was filed with the secretary of state on October 30, 1997:*

(a) An investigation; and

(b) Except as otherwise provided in section 18 of this regulation, 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 section 13 of this regulation.

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 section 20 of this regulation.

Sec. 16. *1. If an application for a license is approved by the administrator of the health division, or his designee, pursuant to sections 4 to 20, inclusive, of this regulation, the health division shall issue a letter of approval to the F.D.A. informing the F.D.A. 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 F.D.A. 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.

Sec. 17. *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 bureau 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 F.D.A., the D.E.A., the state board of pharmacy or the bureau of alcohol and drug abuse.

Sec. 18. *If a facility for treatment with narcotics or a medication unit is accredited by the bureau of alcohol and drug abuse, the health division or the bureau, as appropriate, may accept that accreditation in lieu of conducting a prelicensure survey pursuant to section 15 of this regulation or any other site survey, if the health division or the bureau, as appropriate, receives certification from the bureau of alcohol and drug abuse that the facility or the*

medication unit is accredited and in compliance with all applicable provisions of 21 C.F.R. Parts 291 and 1316.

Sec. 19. *1. The health division may suspend or revoke a license issued pursuant to sections 4 to 20, inclusive, of this regulation 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.

Sec. 20. *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 439.440, inclusive, and sections 1 to 12, inclusive, of LCB File No. R037-97, which was adopted by the state board of health and was filed with the secretary of state on October 30, 1997.*

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 439.440, inclusive, and sections 1 to 12, inclusive, of LCB File No. R037-97.

Sec. 21. NAC 449.013 is hereby amended to read as follows:

449.013 *1. Except as otherwise provided in section 14 of [this regulation,] LCB File No. R035-97, which was adopted by the state board of health and was filed with the secretary of state on October 30, 1997, an applicant for a license to operate any of the following medical*

facilities or programs of hospice care must pay to the health division the following nonrefundable fees:

- (a) An ambulatory surgical center \$1,200
- (b) A facility for the treatment of irreversible renal disease..... 1,200
- (c) A home office or subunit agency of a home health agency 1,200
- (d) A branch office of a home health agency 500
- (e) A rural clinic 1,200
- (f) An obstetric center..... 1,200
- (g) A program of hospice care..... 1,200
- (h) An independent center for emergency medical care..... 1,200
- (i) A nursing pool..... 750
- (j) A facility for treatment with narcotics 750*
- (k) A medication unit 500*

2. An applicant for the renewal of such a license must pay to the health division the following nonrefundable fees:

- (a) An ambulatory surgical center \$600
- (b) A facility for the treatment of irreversible renal disease..... 600
- (c) A home office or subunit agency of a home health agency 600
- (d) A branch office of a home health agency 100
- (e) A rural clinic 600
- (f) An obstetric center..... 600
- (g) A program of hospice care..... 600

(h) An independent center for emergency medical care..... 600

(i) A nursing pool..... 600

(j) A facility for treatment with narcotics 600

(k) A medication unit 100

3. An application for a license is only valid for the calendar year in which the application is submitted. If an applicant does not meet the requirements for licensure imposed by chapter 449 of NRS or the regulations adopted pursuant thereto on or before December 31 of the year in which he submits his application, he must submit a new application and pay the required fee to be considered for licensure.

Sec. 22. Section 2 of LCB File No. R035-97, which was adopted by the state board of health and was filed with the secretary of state on October 30, 1997, is hereby amended to read as follows:

Sec. 2. As used in NAC 449.013, 449.016, 449.0165 and section 14 of **[this regulation,]** *LCB File No. R035-97, which was adopted by the state board of health and was filed with the secretary of state on October 30, 1997,* unless the context otherwise requires, the words and terms defined in sections 3 to 13, inclusive, of **[this regulation]** *LCB File No. R035-97 and sections 2 and 3 of this regulation,* have the meanings ascribed to them in those sections.

Sec. 23. NAC 453.600 and 453.610 are hereby repealed.

Sec. 24. 1. Notwithstanding the provisions of sections 12 and 14 of this regulation, each person or public or private facility that was approved by the health division to operate a facility for treatment with narcotics or a medication unit before the effective date of this regulation

may operate, without a license, the facility for treatment with narcotics or medication unit for which it was approved for a period not to exceed 1 year after the effective date of this regulation.

2. To operate the facility for treatment with narcotics or the medication unit after the period set forth in subsection 1, the person or the public or private facility must file an application for a license pursuant to sections 4 to 20, inclusive, of this regulation not later than 1 year after the effective date of this regulation. If the person or the public or private facility timely files such an application, the person or the public or private facility may continue to operate, without a license, the facility for treatment with narcotics or the medication unit until a final decision on the application for the license has been made pursuant to chapters 439 and 449 of NAC.

TEXT OF REPEALED SECTIONS

453.600 Approval of methadone maintenance programs.

1. No methadone maintenance program may be established or operated until it has been approved by the health division of the department of human resources.

2. Applicants who wish to obtain approval for a methadone maintenance program must submit a copy of their application to the state health officer who, if he finds the application

satisfactory, may issue a letter of approval to accompany the copy of the application to be submitted to the Federal Food and Drug Administration.

3. Copies of all subsequent reports of the activities of the program made to federal authorities must be provided to the state health officer.

453.610 Review of programs.

1. The operation of a methadone maintenance program is subject to the review of the health division. Approval for the program may be withdrawn at any time it is determined that the conditions of NAC 453.600 and applicable federal regulations are not being fulfilled. Notice of denial of an application for approval of a program or withdrawal of approval for a program must comply with the requirements set forth in NAC 439.300 to 439.440, inclusive.

2. An applicant for approval of a program or an operator of an approved program who is aggrieved by the denial of his application or by the withdrawal of approval for the program he is operating may appeal that action in the manner set forth in NAC 439.300 to 439.440, inclusive.