

Title 48
PUBLIC HEALTH GENERAL
Part I. General Administration
Subpart 3. Licensing and Certification
Chapter 74. Minimum Standards/Requirements for
Abuse/Addiction Treatment
Facilities/Programs

Subchapter A. General Provisions

§7401. Definitions and Acronyms

A. The following words and terms when used in this Chapter 74 shall have the following meanings, unless the context clearly states otherwise.

* * *

Accredited the process of review and acceptance by an accreditation body or any additional SAMSHA approved accrediting body such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the Commission on Accreditation of Rehabilitation Facilities (CARF) or Council on Accreditation (COA).

* * *

Opioid Treatment Program a program engaged in opioid treatment of individuals with an opioid agonist treatment medication.

* * *

State Opioid Authority (SOA) the agency designated by the governor or other appropriate official designated by the governor to exercise the responsibility and authority within the state for governing the treatment of opiate addiction with an opioid drug.

* * *

Take Home Dose(s) an opioid agonist treatment medication dose dispensed to patients for unsupervised use for the day(s) the clinic is closed for business, including Sundays and state and federal holidays.

Therapeutic Privilege Dose(s) an opioid agonist treatment medication dose dispensed for unsupervised use, by order of the medical director, to patients compliant with, and stable in, the treatment program for a period of not less than 30 days, under the conditions provided for in §7443.F.1.

* * *

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1058.1-9.

HISTORICAL NOTE: Promulgated by the Health and Human Resources Administration, LR 2:154 (May 1976), amended by the Department of Health and Human Resources, Office of Hospitals, Bureau of Substance Abuse, LR 3:16 (January 1977), amended by the Department of Health and Human Resources, Office of the Secretary, Division of Licensing and Certification, LR 12:26 (January 1986), amended by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 26:1451 (July 2000), LR 31:669 (March 2005).

§7403. Licensing

A. - C.2.f. ...

3. The Department of Health and Human Services, Substance Abuse and Mental Health Services Administration (SAMHSA) promulgated a rule requiring that all Opioid

RULE

Department of Health and Hospitals
Office of the Secretary
Bureau of Health Services Financing

Substance Abuse/Addiction Treatment Facilities Licensing
(LAC 48:I.Chapter 74)

The Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing amends LAC 48:I.Chapter 74 as authorized by R.S. 40:1058.1-9. This Rule is promulgated in accordance with the Administrative Procedure Act, R.S. 49:950 et seq.

The Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing amends the licensing standards for substance abuse/addiction treatment facilities.

Treatment Programs (OTP) shall be accredited by an accreditation body approved by SAMHSA effective May 19, 2004 (*Federal Register*, Volume 66, Number 11, January 17, 2001). If an Opioid Treatment Program is accredited by the Joint Commission on Accreditation of Healthcare Organizations, the Commission on Accreditation of Rehabilitation Facilities or the Council on Accreditation, or any additional SAMSHA approved accrediting body and the OTP requests deemed status from the department, the department may accept such accreditation in lieu of its annual on-site resurvey if the facility forwards their findings to the state agency (i.e., Health Standards Section of the Department) within 30 days of its accreditation. This accreditation will be accepted as evidence of satisfactory compliance with all provisions except those expressed in §§7403.J, K, and L, 7405.A and B, 7407.A, 7409.D, 7411.A, 7413 et seq., and 7417.E.

4. The following set of circumstances can cause the state agency to perform a licensing survey on an accredited OTP:

- a. any valid complaints in the preceding 12-month period;
- b. addition of services;
- c. a change of ownership in the preceding 12-month period;
- d. issuance of a provisional license in the preceding 12-month period;
- e. serious violations of licensing standards or professional standards of practice that were identified in the preceding 12-month period; or
- f. reports of inappropriate treatment or service resulting in death or serious injury.

D. - E.4. ...

F. Off-sites. Related facilities may share a name with the primary facility if a geographic indicator is added to the end of the facility name. All facilities must have a separate license from that issued to the parent facility.

F.1 - F.4. ...

5. Repealed.

G. License Designation. A facility shall have written notification of restrictions, limitations, and services available to the public, community, clients, and visitors.

G.1 - G.2.c. ...

3. Additional Designations (conjointly approved by OAD/HSS in writing)

4. Repealed.

H. - J. ...

K. Notification of Change Requirements. Any change listed below that is not reported in writing to HSS within 10 days is delinquent and subject to sanction. Written approval of changes by DHH is required to remain in compliance with licensure standards.

K.1 - K.2. ...

3. Address Change. Change of address requires issuance of a replacement license. Prior approval is required, and is based on submitting requested information to HSS. The following information and documentation must be submitted to HSS for consideration of an address change:

- a. a complete license application reflecting the new address;
- b. a licensing fee of \$600 for outpatient programs and \$600 plus \$5 per bedroom for inpatient programs;

c. documentation to show that architectural plans and specifications on the new site have been reviewed and approved by the Division of Engineering and Architectural Services;

d. copies of on-site inspection reports performed by the Office of State Fire Marshal and Office of Public Health on the new site;

e. a letter-sized sketch of the new site's floor plan;

f. anticipated effective date of the move; and

g. advise HSS on whether the new site is part of another existing health care entity.

K.4. - K.5. ...

6. Closure. HSS and SOA must be informed of any closure except Sundays and state and federal holidays.

L. - L.2. ...

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§7413. Adverse Action

A. - C.2. ...

3. violation of any provision of this Part or of the minimum standards, rules, or orders promulgated hereunder including, but not limited to:

C.3.a. - E.3. ...

4. Correction of a deficiency is not a basis for an administrative reconsideration or administrative appeal.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1058.1-9.

HISTORICAL NOTE: Promulgated by the Health and Human Resources Administration, LR 2:154 (May 1976), amended by the Department of Health and Human Resources, Office of Hospitals, Bureau of Substance Abuse, LR 3:16 (January 1977), amended by the Department of Health and Human Resources, Office of the Secretary, Division of Licensing and Certification, LR 12:26 (January 1986), amended by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 26:1456 (July 2000), LR 31:670 (March 2005).

Subchapter C. Children/Adolescent Programs

§7427. Children/Adolescent Programs

A. General. Provisions in this §7427 apply to facilities that are inpatient, outpatient, or community based when service recipients are under 18 years of age. The following provisions are in addition to listed requirements for programs, and take precedence over conflicting requirements when services are provided to adolescents or children. Specific programs may have additional requirements in addition to those listed in this §7427.

A.1. - D.12. ...

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Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 26:1464 (July 2000), LR 31:670 (March 2005).

§7429. Primary Prevention Programs

Repealed.

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Subchapter E. Outpatient Programs

§7443. Opioid Addiction Treatment Programs

A. - A.1. ...

2. The goal of all opiate addiction treatment is complete abstinence by the client from all addictive substances, other than those prescribed through the treatment plan.

3. Treatment protocols require that the facility provide medically-approved and medically-supervised assistance to withdraw from the synthetic narcotic when:

- a. the client requests withdrawal;
- b. quality indicators predict successful withdrawal;
- and
- c. client or payor source suspends payment of fees.

4. Each facility is required to independently meet the requirements of the protocols established by OAD/State Opioid Authority.

5. Any program that fails to maintain any required licensure shall be also terminated immediately, pursuant to the provisions of §7413 entitled Adverse Actions.

6. Each program shall also comply with requirements of 42 CFR Part 8 unless the comparable state requirement is more stringent.

7. Each client shall have a documented physical evaluation and examination by a physician or advanced practice registered nurse as follows:

- a. upon admission;
- b. every other week until the client becomes physically stable;
- c. as warranted by patient response to medication during the initial stabilization period or any other subsequent stabilization period;
- d. annually thereafter; and
- e. any time that the client is medically unstable.

B. - B.1.a. ...

- b. individual counseling;
- c. initial treatment plan including initial dose of medication and plan for treatment of critical health or social issues; and
- d. client orientation.

2. Early Stabilization. This phase is the first consecutive 90 days of treatment. Beginning on the third to seventh day of treatment (following initial treatment) through 90 days duration, the following shall be provided:

- a. frequent monitoring by a nurse of the client's response to medication in the first 90 days of treatment. This monitoring must be done at least weekly;
- b. ...

- c. development of a treatment plan within 30 days with input by all disciplines, client and significant others; and

- d. ...

3. Maintenance Treatment. This phase follows the end of early stabilization and lasts for an indefinite period of time. Services to be provided are:

- a. random monthly drug screens until the client has negative drugs-of-abuse screens for 90 days, consecutively. Thereafter, at least eight random drug abuse tests per year shall be performed, as well as random testing for alcohol when indicated. Clients who are allowed six days of therapeutic privilege doses shall be tested every month;

- b. ...

- c. documented reviews of the treatment plan every 90 days in the first two years of treatment by the treatment team; and

- d. ...

4. Withdrawal. Medically supervised withdrawal from the synthetic narcotic with continuing care. This service is provided if and when appropriate. Services to be provided are:

- a. decreasing the dose of the synthetic narcotic to accomplish gradual, but complete withdrawal, as medically tolerated by the client;

- b. ...

- c. discharge planning with continuity of care to assist the client to function without support of the medication and treatment activities.

C. - C.2. ...

3. Written criteria are used to determine when a client will receive additional counseling.

C.4. - D.1.b. ...

- c. approve all transport devices for take home medications in accordance with the program's diversion control policy.

2. Nursing. All medications shall be administered by a practitioner licensed under state law and registered under the appropriate state and federal laws to administer opioid drugs, or by an agency of such a practitioner, supervised by and under the order of the licensed practitioner.

3. ...

4. QPC. There must be a sufficient number of QPCs to meet the needs of the clients, but in no instance shall the ratio exceed 75 clients to one full-time QPC.

D.5. - E.1.a. ...

- b. meets the federal requirements, including exceptions, regarding determination that the client is currently addicted to opiates and has been addicted to opiates for at least one year prior to admission.

2. Physician Verification. The physician shall diagnose the client based upon:

- a. referring medical history and diagnosis of chronic opiate addiction, as currently defined in the Diagnostic and Statistical Manual for Mental Disorders (DSM);
- b. physical examination; and
- c. documented history of opiate addiction.

F. Take Home and Therapeutic Privilege Dose(s). Determinations for therapeutic privilege dose(s) shall be made by the treatment team, documented in the client record, and ordered by the medical director.

1. Client Responsibilities/Considerations Factors. The following must be documented in the client record before a therapeutic privilege dose is authorized by the treatment team.

- a. negative drug/alcohol screens for at least 30 days;
- b. - c. ...
- d. absence of known drug related criminal activity during treatment;
- e. - g. ...

2. Standard Schedule (if indicated)

a. After the first 30 days of treatment, and during the remainder of the first 90 days of treatment, one therapeutic privilege dose per week may be allowed if the treatment team and medical director determine, after consideration of the factors in §7443.F.1 above, that the therapeutic privilege dose is appropriate. Documentation of the determination and of the consideration of each of the factors listed in §7443.F.1 above must be contained in the client record.

b. In the second 90 days of treatment, two therapeutic doses per week may be allowed if the treatment team and medical director determine, after consideration of the factors in §7443.F.1 above, that the therapeutic privilege doses are appropriate. Documentation of the determination and of the consideration of each of the factors listed in §7443.F.1 above must be contained in the client record.

c. In the third 90 days of treatment, three therapeutic doses per week may be allowed if the treatment team and medical director determine, after consideration of the factors in §7443.F.1 above, that the therapeutic privilege doses are appropriate. Documentation of the determination and of the consideration of each of the factors listed in §7443.F.1 above must be contained in the client record.

d. In the final 90 days of treatment of the first year, four therapeutic doses per week may be allowed if the treatment team and medical director determine, after consideration of the factors in §7443.F.1 above, that the therapeutic privilege doses are appropriate. Documentation of the determination and of the consideration of each of the factors listed in §7443.F.1 above must be contained in the client record.

e. After one year in treatment, a six-day dose supply, consisting of take home doses and therapeutic doses, may be allowed once a week if the treatment team and medical director determine, after consideration of the factors in §7443.F.1 above, that the therapeutic privilege doses are appropriate. Documentation of the determination and of the consideration of each of the factors listed in §7443.F.1 above must be contained in the client record.

f. After two years in treatment, a 13-day dose supply, consisting of take home doses and therapeutic doses, may be allowed once every two weeks if the treatment team and medical director determine, after consideration of each of the factors in §7443.F.1 above, that the therapeutic privilege doses are appropriate. Documentation of the determination and of the consideration of each of the factors listed in §7443.F.1 above must be contained in the client record.

3. Loss of Privilege. Positive drug screens at any time for any drug other than those prescribed will require a new determination to be made by the treatment team regarding take-home doses and therapeutic privilege doses.

4. An exception to the standard schedule can only be granted for emergencies and severe travel hardships. The facility must request the exception and obtain approval for the exception from the appropriate federal agency. The facility must retain documentation in the client's clinical record which includes:

- a. documentation by the physician as to the justification for the requested exception; and
- b. documentation of the federal approval or the federal exception.

G. Client Record. Specific additional requirements for documentation include:

- 1. standards of clinical practice regarding medication administration/dispensing;
- 2. results of the five most recent drug screens with action taken for positive results;
- 3. physical status and use of additional prescription medication;
- 4. monthly or more frequently, as indicated by needs of the client, contact notes/progress notes which include employment/vocational needs, legal and social status, overall client stability; and
- 5. any other pertinent information.

H. Training. In addition to orientation as described in §7419, "Staffing Qualification/Requirements," all direct care employees shall receive training and demonstrate knowledge that includes:

- 1. symptoms of opiate withdrawal;
- 2. drug screens and collections, policies and procedures;
- 3. current standards of practice regarding opiate addiction treatment;
- 4. poly-drug addiction; and
- 5. information necessary to assure care is provided within accepted standards of practice.

I. Temporary Transfers or Guest Dosing. The facilities involved shall do the following.

- 1. The receiving facility shall verify dosage prior to administering medication.
- 2. The sending facility shall verify dosage and obtain approval/acceptance from receiving facility prior to client's transfer.

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Frederick P. Cerise, M.D., M.P.H.
Secretary

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