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**State of Louisiana – Department of Health and  
Hospitals Office of Behavioral Health  
Request for Applications (RFA)  
Community Canvassers**

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All Interested Organizations:

The Louisiana Department of Health and Hospitals (DHH) Office of Behavioral Health (OBH) has determined a need exists to expand opioid treatment services in DHH Administrative Regions VIII and IX and is seeking applications from any entity interested and capable of providing opioid treatment services within those designated regions. The following parishes are included in Region VIII: Caldwell, East Carroll, Franklin, Jackson, Lincoln, Madison, Morehouse, Ouachita, Richland, and Tensas, Union and West Carroll. The following parishes are included in Region IX: Livingston, St. Helena, St. Tammany, Tangipahoa and Washington.

**A. Background**

The mission of the Department of Health and Hospitals is to protect and promote health and to ensure access to medical, preventive, and rehabilitative services for all citizens of the State of Louisiana. The Department of Health and Hospitals is dedicated to fulfilling its mission through direct provision of quality services and the utilization of available resources in the most effective manner.

DHH is comprised of the Bureau of Health Services Financing (Medicaid), the Office for Citizens with Developmental Disabilities, the Office of Behavioral Health, the Office of Aging and Adult Services, the Office of Public Health, and the Bureau of Primary Care and Rural Health. Under the general supervision of the Secretary, these principal offices perform the primary functions and duties assigned to DHH. DHH, in addition to encompassing the program offices, has an administrative office known as the Office of the Secretary, a financial office known as the Office of Management and Finance, and various bureaus and boards. The Office of the Secretary is responsible for establishing policy and administering operations, programs, and affairs.

The DHH Office of Behavioral Health is charged with the formulation and implementation of policies relating to the treatment and prevention of alcohol and other drugs of abuse and/or gambling disorders; the administering of residential and outpatient care facilities relating to alcohol and drug abuse or gambling disorders; the establishment of employee assistance programs for state employees; the provision of assessment, referral and treatment services for persons who abuse alcohol and other drugs or have a significant gambling problem and who are subject to the custody of state, municipal, or parish correctional institutions pursuant to agreements with such institutions; and the maintenance of statistics and other relevant information on alcohol, drugs of abuse, and gambling.

**B. Purpose of RFA**

The purpose of this RFA is to solicit applications from qualified organizations interested in providing medication-assisted opioid treatment services for adult opiate addicted males and females in designated regions where OBH has established that a need exists.

**1. Purpose**

The purpose of this Request for Applications is to identify qualified organizations which can show a demonstrated ability to provide medication-assisted opioid treatment services in one or more of the listed geographic areas within a designated region or regions where OBH has determined that a need exists.

**2. Scope**

DHH has determined there is a need to establish opioid treatment programs in DHH Region(s) VIII & IX. LAC 48:I.Chapter 129 specifies once DHH has determined a need for new OTP services, DHH will

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issue a Request for Applications from qualified organizations who can offer the service. Only new programs or additional programs are required to comply with the RFA. The determination of need is based upon the following: Current OTP services are not readily accessible to Louisiana residents in two regions, requiring prospective OTP clients to drive longer than 30 miles from their residence for services

Region VIII: The estimated number of slots needed for Region VIII is 124.

Region IX: The estimated number of slots needed for Region IX is 184.

The date by which the slots need to be available is: February 1, 2013.

The factors the Office of Behavioral Health considered relevant in determining need for new treatment slots include the following criteria:

- 1) the estimated prevalence of opioid addiction in the population of the geographic area to be served; and
- 2) the estimated number of persons in need of medication-assisted treatment for opioid addiction in the geographic area; and
- 3) the estimated treatment demand for medication-assisted opioid addiction treatment in the geographic area to be served; and
- 4) existing access, utilization and availability of medication-assisted opioid addiction treatment in the geographic area to be served.

Data utilized in the determination of need was compiled by the U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration.

### **C. Invitation to Propose**

The Office of Behavioral Health is inviting qualified applicants to submit a proposal to provide opioid treatment services in accordance with the specifications and conditions set forth herein.

### **D. RFA Coordinator**

The response must be in the format of the required Letter of Intent and official OTP Application of Review, be complete upon submission and include the original and eight complete copies including all attachments as required by the application. The letter of intent format and completed application form can be accessed at: <http://new.dhh.louisiana.gov/index.cfm/newsroom/category/48> or requested in writing from:

Michael Gomila, Ph.D.  
Interim State Opioid Treatment Authority  
Department of Health and Hospitals  
Office of Behavioral Health  
DHH - Office of Behavioral Health  
628 N. 4th Street  
P. O. Box 4049  
Baton Rouge, LA 70821-4049  
Fax number: (225)342-5604  
[Email: Michael.Gomila@la.gov](mailto:Michael.Gomila@la.gov)

Opioid Treatment Applications will be scored in the following areas:

1. Applicant's financial viability and availability of funds to support the proposed OTP
2. History of licensure/accreditation and work plan for accreditation and state licensure of proposed OTP
3. Operations/range of services/program design
4. Community integration plan

#### **E. Proposer Inquiries**

DHH Office of Behavioral Health will consider written inquiries regarding the RFA requirements before the date specified in the Schedule of Events. To be considered, written inquiries and requests for clarification of the content of this RFA must be received at the address or via the fax number or email address below by the date specified in the Schedule of Events. All questions directed to the RFA Coordinator will require an official response in writing. Action taken as a result of verbal discussion shall not be binding on DHH Office of Behavioral Health. Only written communication and clarification from the RFA Coordinator shall be considered binding.

RFA Coordinator  
Michael Gomila, Ph.D., Interim State Opioid Treatment Authority  
Louisiana Department of Health and Hospitals  
DHH - Office of Behavioral Health  
628 N. 4th Street  
P. O. Box 4049  
Baton Rouge, LA 70821-4049  
Fax number: (225)342-5604  
[Email: Michael.Gomila@la.gov](mailto:Michael.Gomila@la.gov)

#### **F. Schedule of Events: DHH reserves the right to deviate from this schedule**

<b>Event</b>	<b>Tentative Schedule</b>
<b>Release of RFA</b>	<b>August 29, 2012</b>
<b>Deadline for Receipt of Written Questions</b>	<b>September 12, 2012</b>
<b>Response to Written Questions</b>	<b>September 19, 2012</b>
<b>Submission of Letter of Intent and OTP Application for Review</b>	<b>September 28, 2012</b>
<b>Oral Presentations</b>	<b>TBA</b>
<b>Application Approval Date (60 days from date of application received)</b>	<b>60 days from date of submission of application</b>
<b>Announcement of Selected Applicant Organization</b>	<b>On or by October 29, 2012</b>
<b>OTP program achieves mandated licensure and compliance with all federal, state and local regulations and laws</b>	<b>1 year from date of application approval</b>

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## **G. Response Submittal**

1. Responders interested in providing information requested in the RFA must submit responses containing information specified no later than the deadline for response as stated in the Schedule of Events. Applicants should allow sufficient mail delivery time to ensure receipt of responses by the time specified. The response must be delivered at the applicants' expense to the RFA coordinator. It is solely the responsibility of each responder to ensure their application is delivered prior to the deadline for submission. Responses not received by the deadline will not be considered.
2. Written responses should be submitted with 1 (one) original and 8 (eight) complete copies, and one electronic copy to:

### **For Mail Delivery:**

Michael Gomila, Ph.D.  
Interim State Opioid Treatment  
Authority Louisiana Department  
of Health and Hospitals Office  
of Behavioral Health  
628 N. 4<sup>th</sup> Street P.O. Box 4049  
Baton Rouge, LA 70821-4049  
[Email: Michael.Gomila@la.gov](mailto:Michael.Gomila@la.gov)

### **For Courier Delivery:**

Michael Gomila, Ph.D.  
Interim State Opioid Treatment Authority  
Louisiana Department of Health and  
Hospitals Office of Behavioral Health  
628 North 4<sup>th</sup> Street, 4<sup>th</sup> Floor, Room \_\_\_\_  
Baton Rouge, LA 70821-9278  
[Email: Michael.Gomila@la.gov](mailto:Michael.Gomila@la.gov)

3. Please note all responses are subject to Louisiana's public records law.
4. The following must be included in the response:
  - a. Letter of Intent to inform the DHH Office of Behavioral Health that the applicant requests an OTP Application for Review and to include the following:
    - o the name, address and telephone number of the applicant;
    - o the name of the applicant representative, an individual authorized to respond to department questions regarding the application and who also signs the letter of intent;
    - o the proposed location of the OTP; and
    - o a brief description of the proposed service, and the proposed date of implementation.
  - b. Completed OTP Application for Review Packet with one (1) original and eight (8) complete copies
  - c. Name of organization
  - d. Mailing address and Official Applicant Representative contact information (telephone and fax numbers, and email address)
  - e. Printed name and title of Official Applicant Representative
  - f. Signature of Authorized Representative
  - g. Check made out to the Office of Behavioral Health in the amount of \$600
5. Oral Presentations: The DHH Office of Behavioral Health OTP Application Review Committee will invite applicant organizations to make oral presentations before the committee and respond to questions raised by the committee.
6. Evaluation of the Application: The evaluation of the applications will be based upon the criteria listed below. Evaluations will be conducted by the OTP Application Review Committee. Scoring will be based upon a possible total of 30 points. Each evaluator will score each application and an average sum from each evaluator in each of the following 4 areas will comprise the final committee score.

- a. Financial viability and availability of funds;
- b. Licensure and/or accreditation:
  - i. Work plan for accreditation and state licensure;
  - ii. History of compliance with accreditation, licensure and/or certification bodies related to the provision of healthcare services;
- c. Range of services and program design;
- d. Community integration:
- i. Availability, accessibility and appropriateness of the location of the proposed OTP site; (for example: accessibility to public transportation and healthcare providers; location in relation to children's schools and playgrounds);
- ii. Methods to achieve community integration through a community relations plan.

Criteria	Possible Score
Financial viability and availability of funds for proposed OTP	10
History of and current plan for accreditation/licensure of proposed OTP	10
Operations/range of services/program design	5
Community integration plan	5

7. Announcement of Award: DHH Office of Behavioral Health will notify the successful applicant as per the Schedule of Events.

8. Other Logistics:

- a. Contact after Solicitation Deadline: After the date for receipt of applications, no application-initiated contact relative to the solicitation will be allowed between the applicant and DHH until the award announcement is made.
- b. Rejection and Cancellation: Issuance of this solicitation does not constitute a commitment by DHH Office of Behavioral Health to award an approved application. DHH Office of Behavioral Health reserves the right to reject any or all proposals received in response to this solicitation.
- c. Completeness of Information: Failure to furnish mandatory information specifically required in this solicitation or required number of copies shall disqualify an applicant.
- d. Proprietary Information: Only information which is in the nature of legitimate trade secrets or non-published financial data may be deemed proprietary or confidential. Any materials within an application identified as such must be clearly marked in the application and will be handled in accordance with the Louisiana Public Record Act R. S. 44:1-44, and applicable rules and regulations. Any application marked as confidential or proprietary in its entirety may be rejected without further considerations or recourse.

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- e. In the event it becomes necessary to revise any portion of the RFA for any reason, the Department shall post addenda, supplements, and/or amendments to all potential proposers known to have received the RFA. Additionally, all such supplements shall be posted at the following web address: <http://new.dhh.louisiana.gov/index.cfm/newsroom/category/48>

Attachments:

- 1- Enabling Legislation
- 2- Administrative Rule
- 3- SAMHSA Accreditation Guidelines
- 4- CARF OTP Standards Checklist
- 5- State Licensing Standards

# ACT No. 166

Regular Session, 2008

HOUSE BILL NO. 1062

BY REPRESENTATIVE MILLS

1 AN ACT

2 To amend and reenact R.S. 40:1058.3(C), relative to methadone maintenance programs; to  
3 extend the moratorium on methadone maintenance programs; to provide that the  
4 Department of Health and Hospitals may license a new or additional methadone  
5 maintenance program if a need is determined to exist; to provide for the  
6 promulgation of rules and regulations; to provide for a special effective date; and to  
7 provide for related matters.

8 Be it enacted by the Legislature of Louisiana:

9 Section 1. R.S. 40:1058.3(C) is hereby amended and reenacted to read as follows:

10 §1058.3. Licensing of substance abuse/addiction treatment facilities; applications;  
11 fees; disposition of fees; moratorium on methadone maintenance clinics  
12 programs; exceptions

13 \* \* \*

14 C.(1) A moratorium is declared upon the certification licensure of additional  
15 methadone maintenance programs. The moratorium shall become enforceable on  
16 July 1, 2003, and shall remain in effect until July 1, 2008 2010. During the  
17 moratorium, the Department of Health and Hospitals shall undertake a study to  
18 determine the need for and the criteria for certification of methadone clinics which  
19 shall be completed and a report thereon submitted to the House Committee on Health  
20 and Welfare and to the Senate Committee on Health and Welfare not later than  
21 January 15, 2008. The state department shall not approve license any additional  
22 methadone maintenance programs prior to July 1, 2008 2010.

23 (2) Notwithstanding the provisions of Paragraph (1) of this Subsection, if the  
24 department determines, in its discretion, that there is a need for new or additional





1 methadone maintenance programs in a certain geographic location, the department  
2 may license a new or additional methadone maintenance program. The department  
3 is authorized to promulgate and adopt rules and regulations in accordance with the  
4 Administrative Procedure Act to provide for the following:

5 (a) Criteria and processes for determining whether such a need exists.

6 (b) Procedures for selecting a methadone maintenance program to be  
7 licensed once a need has been determined.

8 (3) The provisions of this Subsection shall apply only to applications for new  
9 programs not approved prior to July 1, 2001.

10 Section 2. This Act shall become effective on July 1, 2008; if vetoed by the governor  
11 and subsequently approved by the legislature, this Act shall become effective on July 1,  
12 2008, or on the day following such approval by the legislature, whichever is later.

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SPEAKER OF THE HOUSE OF REPRESENTATIVES

\_\_\_\_\_  
PRESIDENT OF THE SENATE

\_\_\_\_\_  
GOVERNOR OF THE STATE OF LOUISIANA

APPROVED: \_\_\_\_\_

**Title 48**  
**PUBLIC HEALTH—GENERAL**  
**Part I. General Administration**  
**Subpart 5. Health Planning**

**Chapter 129. Opioid Treatment Program (OTP) Need and Application Reviews**

**Subchapter A. General Provisions**

**§12901. Definitions**

A. Definitions. When used in this Chapter the following terms and phrases shall have the following meanings unless the context requires otherwise.

*Applicant*—the individual or legal entity who is applying to open an OTP.

*Applicant Representative*—the person specified by the applicant on the application form who is authorized to respond to Department of Health and Hospital questions regarding the OTP application review process and to whom written notifications are sent relative to the status of the application during the review process.

*Applicant Review Period*—the period of time in which the review is conducted.

*Approval*—a determination by the Department of Health and Hospitals (DHH) that an application meets the criteria of the OTP application review.

*Approved*—opioid treatment programs which are grandfathered in accordance with the grandfather provisions of this program and/or opioid treatment programs approved in accordance with the OTP application review.

*Committee*—The Opioid Treatment Program (OTP) application review committee.

*Department*—the Department of Health and Hospitals (DHH) in the state of Louisiana. The following is a list of pertinent sections.

*DHH Administrative Regions*—The administrative regions and the parishes which comprise these regions are as follows:

- a. Region I: Orleans, Plaquemines, Jefferson, and St. Bernard;
- b. Region II: Ascension, East Baton Rouge, East Feliciana, Iberville, Pointe Coupee, West Baton Rouge, and West Feliciana;
- c. Region III: Assumption, Lafourche, St. Charles, St. James, St. John, St. Mary, and Terrebonne;
- d. Region IV: Acadia, Evangeline, Iberia, Lafayette, St. Landry, St. Martin, and Vermilion;
- e. Region V: Allen, Beauregard, Calcasieu, Cameron, and Jefferson Davis;
- f. Region VI: Avoyelles, Catahoula, Concordia, Grant, LaSalle, Rapides, Vernon, and Winn;
- g. Region VII: Bienville, Bossier, Caddo, Claiborne, DeSoto, Natchitoches, Red River, Sabine, and Webster;
- h. Region VIII: Caldwell, East Carroll, Franklin, Jackson, Lincoln, Madison, Morehouse, Ouachita, Richland, Tensas, Union, and West Carroll; and
- i. Region IX: Livingston, St. Helena, St. Tammany, Tangipahoa, and Washington.

*Health Standards Section (HSS)*—Section of Bureau of Health Services Financing, DHH that surveys, licenses and serves as the regulatory body for health care facilities in the state, including opioid treatment programs.

*Methadone Maintenance Program*—see Opioid Treatment Program.

*Notification*—is deemed to be given on the date on which a decision is mailed by DHH by certified mail to the last known address of the applicant.

*Office for Addictive Disorders (OAD) or its successor organization*—DHH office and single state agency that is statutorily responsible for the treatment and prevention of addictive disorders.

*Opioid Treatment Program (OTP)*—a program engaged in medication-assisted opioid treatment of individuals with an opioid agonist treatment medication.

*Opioid Treatment Program Application Review*—a review of applications to select an OTP to be licensed once a need has been determined.

*Opioid Treatment Program Need Review*—a review to determine whether there is a need for new or additional OTPs in a certain geographic location.

*Secretary*—the Secretary of the DHH.

*State Opioid Treatment Authority*—the OAD authority within DHH designated to exercise the responsibility and authority within the state for governing the treatment of opiate addiction with an opioid drug.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1058.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office for Addictive Disorders, LR 36:521 (March 2010).

**§12903. General Information**

A. No opioid treatment program may be licensed in the state of Louisiana after July 1, 2001 unless the department has determined, in its discretion, that there is a need for new or additional opioid treatment programs in a certain geographic location. The department will provide criteria and processes for determining whether such a need exists and procedures for selecting an opioid treatment program to be licensed once a need has been determined. An offsite location and/or a mobile site of an existing OTP clinic is considered a new OTP and, as such, must receive approval of the department OTP need and applications reviews.

1. The department shall conduct an OTP need review to determine if there is a need for new or additional opioid treatment programs in a certain geographic location.

2. Once the need has been determined, the department will issue a request for applications for new or additional OTPs.

3. The department shall conduct an OTP application review.

4. Once the application review approval is granted, the OTP is then eligible to apply for a license from the department.

B. The duties of the department under this opioid treatment program (OTP) need review and application review include, but are not limited to:

1. defining the appropriate methodology for the collection of data necessary for the administration of the OTP need review; and

2. developing the application review process.

C. Grandfather Provision. An approval shall be deemed to have been granted without OTP need or application review for OTPs that were licensed and approved in Section 7403 prior to July 1, 2001.

D. OTP application review approvals are non-transferable. Approvals for licensed OTPs are limited to the name of the original licensee and to the location unless exempted from the need and application reviews.

1. For all OTPs undergoing a change of ownership after July 1, 2010, including those OTPs who qualify for the Grandfather Provision, the buyer must submit a new application and obtain approval from the OTP application review committee prior to the change of ownership.

2. For all OTPs undergoing a change in location after July 1, 2010, including those OTPs who qualify for the Grandfather Provision, the owner must submit a new application and obtain approval from the OTP application review committee prior to the change of location.

E. Exemptions from OTP Need Review and Application Review

1. Exemptions from OTP need review and application review shall be made for OTP clinics that meet the following criteria:

a. an OTP clinic is replaced due to destruction by fire or a natural disaster, such as a hurricane, and is closed no longer than eight months; or

b. an OTP clinic is replaced due to potential health hazard in the clinic and is closed for no longer than 150 days.

2. One extension of no more than three months may be granted upon the documentation of good cause, provided the extension is requested no later than one month from the original deadline.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1058.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office for Addictive Disorders, LR 36:522 (March 2010).

#### **Subchapter B. Determination of Need**

##### **§12905. Opioid Treatment Program Need Review**

A. The OTP need review includes criteria and processes to determine the need for new or additional OTPs in a certain geographic location within an identified DHH administrative region.

B. Determination of Need

1. The department will determine need through a review and evaluation of the following criteria:

a. estimated prevalence of opioid addiction in the population of the geographic area to be served; and

b. estimated number of persons in need of medication-assisted treatment for opioid addiction in the geographic area; and

c. estimated treatment demand for medication-assisted opioid addiction treatment in the geographic area to be served; and

d. existing access, utilization and availability of medication-assisted opioid addiction treatment in the geographic area to be served.

2. A determination of need will utilize data sources that include information compiled and recognized by the department and/or any of the following: Substance Abuse and Mental Health Services Administration (SAMHSA), the United States Census Bureau, the Drug Enforcement

Administration (DEA) and the National Institute on Drug Abuse (NIDA).

C. The department may conduct additional need reviews only when special needs and circumstances arise which indicate the need for additional medication-assisted opioid addiction treatment services, such as increased utilization rates, reduced availability, and/or reduced accessibility of services.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1058.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office for Addictive Disorders, LR 36:523 (March 2010).

#### **Subchapter C. Procedure for Selection of Opioid Treatment Program**

##### **§12907. Opioid Treatment Program Application Review**

A. If the department determines that there is a need for services in a DHH region, the department will issue a request for applications (RFA) announcement statewide through the Louisiana Press Association. The RFA will specify the dates during which the department will accept applications.

B. No applications will be accepted under these provisions unless the department declares a need and issues an RFA.

C. Any applicant to open an OTP must adhere to all policies, rules and regulations set forth by the State of Louisiana and the Department of Health and Hospitals. Services shall be provided in accordance with standards set forth by SAMHSA, DHH Health Standards, the US Department of Justice/Drug Enforcement Administration (DEA), the Louisiana Board of Pharmacy and all applicable, SAMHSA-approved accrediting bodies.

D. Any applicant to open an OTP shall be free of any conviction for, or guilty plea, or plea of nolle contendere to a felony. If the applicant is an agency, the owners of that agency must be free of such felony convictions.

E. The OTP request for applications will indicate which department administrative region is in need of openings, or slots, for clients; the number of slots needed, the date by which the slots need to be available to the target population and the factors which the department considered relevant in determining the need for the treatment slots. The OTP request for applications will specify the type of information on which the determination of need was based.

F. OTP applications shall be submitted to the DHH Office for Addictive Disorders, State Opioid Treatment Authority.

1. Application forms shall be requested in writing or by telephone from the Office for Addictive Disorders, State Opioid Treatment Authority, who will provide application forms, criteria utilized to determine need and other materials relevant to the application process.

2. The applicant representative specified on the application will be the only person to whom the DHH Office for Addictive Disorders will send written notification in matters relative to the status of the application during the review process. If the applicant representative or his address changes at any time during the review process, the applicant shall notify the DHH Office for Addictive Disorders, State Opioid Treatment Authority, in writing.

3. A prospective OTP applicant shall submit the following documents as part of the application:

a. a letter of intent to inform the department that the applicant requests an OTP application review and to include the following:

- i. the name, address and telephone number of the applicant;
- ii. the name of the applicant representative, an individual authorized to respond to department questions regarding the application and who also signs the letter of intent;
- iii. the proposed location of the OTP; and
- iv. a brief description of the proposed service, and the proposed date of implementation;

b. an original and three copies of the application. An application shall be submitted on forms provided for that purpose, contain such information as the department may require, and be accompanied by a nonrefundable fee of \$600.

4. Applications will be accepted for a period to be specified in the request for application.

5. Once submitted, an application cannot be changed and additional information will not be accepted.

6. Submitted applications failing to meet these guidelines or without the required fee will not be processed and will be returned to the applicant.

G. The OTP committee shall be appointed by the Secretary of the Department of Health and Hospitals. DHH appointments to the OTP committee shall include the following members:

1. DHH OAD Medical Director or physician who has expertise in substance abuse treatment and, in particular, opioid treatment;

2. Executive Director of the DHH Office for Addictive Disorders program service region or district in which the proposed OTP would be located;

3. licensed addiction counselor approved by the Louisiana Addictive Disorder Regulatory Authority and DHH Office for Addictive Disorders;

4. member of the Louisiana Board of Pharmacy;

5. Louisiana State Opioid Treatment Authority;

6. current President of the State Opioid Treatment Authority Alliance or a State Opioid Treatment Authority from another state; and

7. DHH OAD Fiscal Director.

H. No committee member shall have a proprietary, financial, professional or other personal interest of any nature or kind in any OTP.

I. The applicant shall make a brief presentation of the proposed program before the committee and respond to questions raised by the committee.

J. The department sets the review period, which will be no more than 60 days, except as noted below. The review period begins on the first day after the date of receipt of the application.

1. A longer review period will be permitted only when initiated by the committee. A maximum of 30 days will be allowed for an extension.

2. An applicant may not request an extension of the review period, but may withdraw an application (in writing) at any time prior to the notification of the decision by the DHH Office for Addictive Disorders.

K. The committee will review the applications and independently evaluate and assign points in each of the following subject areas for the quality and adequacy of the applicant's responses:

1. financial viability and availability of funds;
2. licensure and/or accreditation:
  - a. work plan for accreditation and state licensure;
  - b. history of compliance with accreditation, licensure and/or certification bodies related to the provision of healthcare services;
3. range of services and program design;
4. community integration:
  - a. availability, accessibility and appropriateness of the location of the proposed OTP site; (for example: accessibility to public transportation and healthcare providers; location in relation to children's schools and playgrounds);
  - b. methods to achieve community integration through a community relations plan.

L. A score will be given to the applicants' responses on the application.

M. The approved highest scoring application will then be forwarded to the DHH Secretary for final approval.

N. Upon the secretary's final approval, the Office for Addictive Disorders State Opioid Treatment Authority will forward a notice of approval letter to the applicant representative.

O. Each applicant will be notified of the department's decision. Notification shall be sent by certified mail to the applicant representative.

P. Notification shall be sent to the applicant at his last known address. An applicant is responsible for notifying the department of any change of address.

Q. Applications approved under these provisions are bound to the description in the application with regard to opioid treatment as well as to the location. The OTP application review approval shall expire if these aspects of the application are altered, except as noted below.

1. If, due to no fault of the approved OTP applicant, the location fails, the applicant has 30 days from the application approval date to secure an alternate location and submit the location to the committee.

2. The committee will approve or deny the alternate location within 15 days of submittal.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1058.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office for Addictive Disorders, LR 36:523 (March 2010).

#### **Subchapter D. Administrative Appeals**

##### **§12909. Appeal Procedures**

A. Upon denial of the department to grant an OTP proposal review approval, only the applicant shall have the right to request an administrative appeal.

1. A written request for such an appeal must be submitted to the secretary within 30 days after the notification of the denial is received by the applicant.

2. The request shall contain a statement setting forth the specific reasons the applicant disagrees with the denial.

3. All administrative appeals shall be consolidated for purposes of the hearing.

##### **B. Administrative Hearings**

1. The hearings shall be conducted at the DHH Bureau of Appeals in accordance with the Administrative Procedures Act.

2. Any party may appear and be heard at any appeal proceeding through an attorney or designated representative. A person appearing in a representative capacity shall file a

written notice of appearance on behalf of the provider identifying his/her name, address, telephone number and the party being represented.

3. The hearing shall be conducted within 60 days after receipt of the written request for the hearing. Either party may request an extension of the hearing date upon a showing of good cause provided that the hearing is rescheduled to a date no later than 120 days from receipt of notice of the department's decision.

4. The Bureau of Appeals may schedule a preliminary conference. If one is scheduled, the parties shall be notified in writing of the date, time and place of the conference.

5. The applicant and department will be notified in writing of the date, time and place of the administrative hearing no later than 15 calendar days prior to the hearing.

6. An applicant who has requested an administrative appeal shall present his case first and has the burden to show by a preponderance of the evidence that his application should have been approved by the department pursuant to the provisions of this rule. After the applicant has presented his evidence, the department will then have the opportunity to present its case and to refute and rebut the testimony and evidence presented by the applicant.

7. If an applicant fails to appear at the administrative hearing, a decision shall be issued by the Bureau of Appeals dismissing the appeal. The dismissal may be rescinded upon order of the Bureau of Appeals if the applicant makes written application within 10 calendar days following the mailing of the dismissal order and provides evidence of good cause for the failure to attend the hearing.

C. The issuance of the approval shall be suspended if an applicant files an appeal. The suspension is effective only during the administrative appeal process.

D. Within 20 days of the completion of the hearing, The Bureau of Appeals shall make a written decision. The written decision shall be final, binding and enforceable. A copy of the decision shall be mailed to the applicant at his last known address or to his authorized representative.

E. An applicant has the right to file for judicial review in accordance with the Administrative Procedures Act.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1058.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office for Addictive Disorders, LR 36:524 (March 2010).

### **§12911. Licensing and Certification Compliance**

A. The following time frames shall apply for complying with the requirements for obtaining DHH licensure as an opioid treatment program and for complying with all applicable federal, state, and local laws and regulations.

1. Opioid treatment programs shall achieve DHH licensure no later than one year from the date of the OTP application review approval.

2. OTPs shall be in compliance with all applicable OTP federal, state, and local laws and regulations no later than one year from the date of the OTP application review approval.

B. Failure to meet the timeframes in this section could result in an automatic expiration of the OTP application review approval of the OTP.

C. An OTP that intends to relinquish application review approval prior to the expiration of the timeframes in this Section, shall submit a letter of such intent to the DHH Office for Addictive Disorders State Opioid Treatment Authority.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1058.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office for Addictive Disorders, LR 36:525 (March 2010).

### **Subchapter E. Rescission of OTP Need Review Application Approvals**

#### **§12913. General Provisions**

A. Opioid treatment program application review approval shall be automatically rescinded upon rendering of a final decision under the following circumstances:

1. a clinic's license is revoked;
2. a clinic's license is not renewed;
3. a clinic's license is denied;
4. a clinic's license is voluntarily surrendered;
5. a cessation of the clinic's business;
6. a clinic's accreditation is revoked;
7. a clinic's accreditation is not renewed;
8. a clinic's accreditation is denied.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1058.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office for Addictive Disorders, LR 36:525 (March 2010)

# **Guidelines for the Accreditation of Opioid Treatment Programs**

**Revised July 20, 2007**

## Contents

1. Introduction.....	1
2. Opioid Treatment Standards .....	3
A. Administrative Organization and Responsibilities .....	3
B. Management of Facility and Clinical Environment.....	4
C. Risk Management and Continuous Quality Improvement .....	5
D. Diversion Control .....	8
E. Professional Staff Credentials and Development .....	9
F. Patient Admission Criteria.....	10
G. Informed Consent .....	11
H. Patient Medical and Psychosocial Assessment.....	12
I. Pregnant and Postpartum Patients .....	15
J. Concurrent Pregnancy and HIV Infection .....	17
K. Neonatal Abstinence Syndrome .....	17
L. Treatment Planning, Evaluation of Patient Progress in Treatment, and Continuous Clinical Assessment .....	17
M. Detoxification, Tapering, or Medically Supervised Withdrawal.....	19
N. Medically Supervised Withdrawal From Medication.....	19
O. Administrative Withdrawal and Discharge .....	21
P. Continuing Care.....	21
Q. Additional Treatment Planning Considerations.....	22
R. Concurrent Services.....	26
S. Testing for Drug Use .....	28
T. Record Keeping and Documentation.....	29
U. Guidelines for Therapeutic Dosage .....	32
V. Unsupervised Approved Use (Take-Home Medication) .....	35
W. Patients' Rights.....	36
Endnotes.....	41
Appendix A. References .....	49
Appendix B. Guideline Panel .....	50
Appendix C. Frequently Asked Questions.....	54
Appendix D. Standard and Example Forms.....	63
Appendix E. Index .....	70

**Statement of Nonbinding Effect—This guidance document represents the Agency’s current thinking on the Federal Opioid Treatment Standards set forth under 42 CFR § 8.12. It does not create or confer any rights for or on any person or program and does not operate to bind the Substance Abuse and Mental Health Services Administration (SAMHSA) or the public. An alternative approach may be used if such an approach satisfies the requirements of applicable statutes and regulations.**

## 1. Introduction

The Center for Substance Abuse Treatment (CSAT) developed the original Guidelines for the Accreditation of Opioid Treatment Programs (OTPs) between 1996 and 1999, using a Treatment Improvement Protocol (TIP) type process, involving two expert panels, field reviews, and clearances from other Federal agencies and the Office of Management and Budget. These guidelines were established to serve as a guide to accreditation organizations in developing accreditation standards, which conform with the Substance Abuse and Mental Health Services Administration's (SAMHSA) Federal Opioid Treatment Standards, found in Title 42 of the Code of Federal Regulations (CFR), Part 8. The guidelines also provide guidance to OTPs, elaborating on and providing examples of ways in which programs can achieve and maintain compliance with Federal regulations.

OTPs must be certified by SAMHSA before they may dispense opioid drugs in the treatment of opioid addiction. To become certified, an OTP must meet the Federal opioid treatment standards in section 8.12 of the regulation, must have current valid accreditation status from a SAMHSA-approved accreditation body, and must comply with any other conditions for certification established by SAMHSA. Under Title 42 of CFR Part 8 (42 CFR Part 8) which became effective in May 2001, an accreditation organization or State governmental entity that wants to participate in SAMHSA's OTP certification program must apply to become a SAMHSA-approved accreditation body. Among the numerous application requirements, potential accreditation bodies are required to submit a set of accreditation elements and a detailed discussion showing how these ensure that each OTP surveyed is qualified to meet the Federal opioid treatment standards set forth in section 8.12 of the regulations.

The experience gained from the application of the rules and the thousands of accreditation surveys conducted since 2001 have identified issues and areas that would benefit from careful review and update. Because the accreditation guidelines have not been updated since 1999, and have not been substantially reviewed and revised by experts since 1998, an Expert Panel was convened in October–November 2005. The panel was charged with revisiting and revising the guidelines in light of new scientific research findings, advancements in the field, and state-of-the-art, evidence-based practices. Expert panel members were selected based on their knowledge and expertise of the following content areas:

- The most recent developments in opioid addiction treatment
- The prevention and treatment of infectious diseases, such as HIV and hepatitis viruses
- Best practices and standards of practice
- The addition of buprenorphine to the armamentarium of available treatment medications
- The growing problem of prescription drug abuse
- Issues relating to diversion control
- Medication for unsupervised or take-home use
- Methadone-associated mortality
- Planning and acting in emergencies
- Detoxification from drugs of abuse
- Medically supervised withdrawal from opioids
- Community or State resistance to medication-assisted treatment
- Cardiac complications
- Pain management



- Third-party reimbursement

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- Physician and staff education
- Office-based treatment

SAMHSA is committed to Good Guideline Practices, and such practices include periodic review and update of guidelines as evidence and experiences associated with best practices advance. SAMHSA announced the availability of the revised draft guideline in the Federal Register published April 21, 2006. The notice provided information on how to obtain the draft and submit comments during the 60-day comment period. CSAT values the careful thought and attention members of the opioid treatment community gave to the draft guidelines, thus staff carefully considered and reviewed all comments and modified the guidelines as appropriate.

OTPs should be aware of their obligation to protect the confidentiality of patient substance abuse patient records, as set forth in Federal regulations at Title 42 of the Code of Federal Regulations, Part 2. Patient privacy becomes especially important with the national movement toward electronic health records. Additional information about privacy and substance abuse treatment is available at <http://hipaa.samhsa.gov/privacyrule.htm>.

To understand some of the guidelines, the reader may need a more complete explanation of the issue or rationale underlying the standard, as well as some examples to clarify meaning. Superscript letters guide the reader to that information in endnotes, pages 41–47. Additionally, text boxes above each relevant section in the guidelines directly excerpt the text from 42 CFR so that the reader may reference both the guidelines and the regulations concurrently.

Should there be any questions or issues not covered in this guidance document, please contact CSAT's Division of Pharmacologic Therapies (DPT) at 1–240–276–2700.

## 2. Opioid Treatment Standards

### 42 CFR § 8.12 Federal Opioid Treatment Standards

(a) *General.* OTPs must provide treatment in accordance with the standards in this section and must comply with these standards as a condition of certification.

(b) *Administrative and organizational structure.* An OTP's organizational structure and facilities shall be adequate to ensure quality patient care and to meet the requirements of all pertinent Federal, State, and local laws and regulations. At a minimum, each OTP shall formally designate a program sponsor and medical director. The program sponsor shall agree on behalf of the OTP to adhere to all requirements set forth in this part and any regulations regarding the use of opioid agonist treatment medications in the treatment of opioid addiction, which may be promulgated in the future. The medical director shall assume responsibility for administering all medical services performed by the OTP. In addition, the medical director shall be responsible for ensuring that the OTP complies with all applicable Federal, State, and local laws and regulations.

42 CFR § 8.2 *Medical director* means a physician, licensed to practice medicine in the jurisdiction in which the opioid treatment program is located, who assumes responsibility for administering all medical services performed by the program, either by performing them directly or by delegating specific responsibility to authorized program physicians and healthcare professionals functioning under the medical director's direct supervision.

*Program sponsor* means the person named in the application for certification described in § 8.11(b) is responsible for the operation of the opioid treatment program and who assumes responsibility for all its employees, including any practitioners, agents, or other persons providing medical, rehabilitative, or counseling services at the program or any of its medication units. The program sponsor need not be a licensed physician but shall employ a licensed physician for the position of medical director.

42 CFR § 8.11(f) (5) OTPs shall notify SAMHSA within 3 weeks of any replacement or other change in the status of the program sponsor or medical director.

### A. Administrative Organization and Responsibilities

Administrative responsibilities, both for organizations and individual practitioners, are adequate to ensure quality patient care and to meet the requirements of the laws and regulations of the Federal Government, the Department of Health and Human Services (HHS), the Drug Enforcement Administration (DEA), and the States.

Physician authority over the medical aspects of treatment is essential. Physicians retain the autonomy to make continuing treatment decisions in accord with clinical course and emergent research findings.

It is essential to develop a referral and consultative relationship with a network of agencies and providers capable of providing primary and specialty services for the range of psychiatric comorbid conditions, medical complications, and communicable diseases that may be part of a patient's problem list. Information exchange across this network must both facilitate treatment and protect patient privacy.

#### (1) Goals

Each treatment program should have a statement of its goals for patient care.

#### (2) Human Resources Management

(a) Each treatment program has a plan to ensure that staffing patterns are appropriate and adequate for the needs of the patients served.

- (b) Programs maintain individualized personnel files as a record of employment. These files contain employment and credentialing data deemed appropriate by the employer. The files also contain employment application data, date of employment, updated licensing and credentialing data, detailed job descriptions, performance evaluations, and appropriate intramural and extramural training records.

## **B. Management of Facility and Clinical Environment**

### **(1) Each treatment facility**

- (a) Has sufficient space and adequate equipment for the provision of all specified services, including diagnosis, evaluation, and treatment of other medical, psychiatric, and behavioral disorders, if they are to be carried out onsite
- (b) Is clean and well maintained, similar to and consistent with other treatment facilities for different medical and behavioral disorders
- (c) Maintains documentation that it meets all local and State safety and environmental codes
- (d) Ensures protection of confidentiality, including the use of locked files and the availability of private, individual offices for counseling
- (e) Provides services during hours that meet the needs of the overwhelming majority of patients, including hours before and/or after the traditional 8:00 a.m. to 5:00 p.m. working day, when possible

- (2)** The program sponsor is the person ultimately responsible for the operation of the program. Importantly, the program sponsor is responsible for assuring that the program complies with all Federal, State, and local laws and regulations. (See 42 CFR § 8.2.) If there is a change of sponsor, SAMHSA requires formal notification within 3 weeks of the change.

- (3)** The program director or program manager is the person who manages the program operations from day to day, and whose authority is delegated by the program sponsor (who retains ultimate responsibility for program operations). Program directors have varying levels of program responsibility, frequently including the responsibility to hire and fire employees, and carry out multiple management activities, depending on the duties assigned to them by the sponsor. (Not all programs have program directors or program managers, and the regulations do not require them. In some OTPs, the program sponsor also acts as the program director.)

- (4)** The medical director is responsible for monitoring and supervising all medical services provided by the OTP. In some cases, the medical director serves as the program sponsor; however, only a licensed physician may serve as the medical director of an OTP. (See 42 CFR § 8.2.) If there is a change of medical director, SAMHSA requires formal notification within 3 weeks of the change.

42 CFR 8.12(c) *Continuous quality improvement.* (1) An OTP must maintain current quality assurance and quality control plans that include, among other things, annual reviews of program policies and procedures and ongoing assessment of patient outcomes.

## **C. Risk Management and Continuous Quality Improvement**

### **(1) Life Safety Issues**

#### **(a) Each treatment program**

- (i) Develops procedures to ensure that the correct dose of medication(s) is administered and that appropriate actions are taken if a medication error is made. Procedures should include a mechanism for reporting untoward incidents to appropriate program staff.
- (ii) Provides a mechanism to address patient emergencies by establishing an emergency contact system to obtain dosage levels and other pertinent patient information on a 24-hour, 7-day-a-week basis, as appropriate under confidentiality regulations. Facility offices and waiting areas should display the names and telephone number of individuals (e.g., physicians, hospitals, emergency medical technicians) who should be contacted in case of emergency, or utilize 9–1–1 or similar local emergency resources.
- (iii) Ensures that there are appropriately trained staff members on duty who are trained and proficient in cardiopulmonary resuscitation (CPR), management of opiate overdose, medical emergencies, and other techniques as appropriate.
- (iv) Establishes policies and procedures that address safety and security issues for patients and staff, including training for staff to handle physical or verbal threats, acts of violence, inappropriate behavior, or other escalating and potentially dangerous situations, with emphasis on situations in which security guards or police need to be summoned.

#### **(b) Program Emergencies<sup>a</sup>**

##### Each treatment program

- (i) Develops, maintains, and updates regularly a disaster plan that addresses maintenance of fire extinguishers, fire drills, emergency evacuation procedures, and that includes links to community agencies.
- (ii) Maintains a 24-hour telephone answering capability to respond to facility emergencies. A record of patients and medication dosages is accessible to the staff person on call for verification purposes.
- (iii) Maintains an up-to-date plan for emergency administration of medications in case the program must be closed temporarily. The plan should include a mechanism for informing patients of these emergency arrangements.
- (iv) Ensures that needed supplies are available in the event of an emergency.

**(2) Continuous Quality Improvement<sup>b</sup>**

Each treatment program

- (a) Provides regular and continuous staff education.
- (b) Maintains staff development plans.
- (c) Reviews and recertifies program policies and procedures at least annually.
- (d) Elicits ongoing input into program policies and procedures by patients in consideration of community concerns.
- (e) Develops and implements periodic patient satisfaction surveys.
- (f) Adheres to universal or standard infection control precautions promulgated by the Centers for Disease Control and Prevention (CDC).
- (g) Measures and monitors treatment outcomes and processes on a regular basis—for example, quarterly—to provide feedback on measures of performance. Monitors and measures treatment outcomes such as
  - (i) Reducing the illicit use of illicit opioids, illegal drugs, and the problematic use of alcohol and prescription medicines
  - (ii) Reducing associated criminal activities and entry into the criminal justice system
  - (iii) Reducing behaviors contributing to the spread of infectious diseases
  - (iv) Improving quality of life by restoring physical and mental health and functional status
  - (v) Increasing retention in treatment
  - (vi) Increasing numbers of patients who are employed
  - (vii) Increasing abstinence from drugs of abuse

**(3) Events That Require Immediate Response and Investigation<sup>c</sup>**

Each treatment program

- (a) Establishes procedures to guard against critical incidents, which are defined as any events that could have a negative impact on patients and their family members and the program or staff. This includes events that involve the loss of life or function, any serious physical or psychological injury, and medication errors. Critical events are also known as sentinel events, significant adverse events, and untoward events.
- (b) Establishes procedures, in case a critical incident occurs, to ensure
  - (i) Full documentation of the incident
  - (ii) Prompt investigation and review of the situation surrounding the incident
  - (iii) Implementation of timely and appropriate corrective action(s)

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**(iv) Ongoing monitoring of any corrective actions until their effectiveness is established**

- (c) Reports each critical incident to the accrediting organization in accordance with procedures established by these organizations. Examples of reportable critical incidents involving patient deaths include:
- (i) Drug-related deaths
  - (ii) Methadone or buprenorphine deaths
  - (iii) Unexpected or suspicious deaths
  - (iv) Treatment-context deaths that raise individual, family, community, or public concern
- (d) As appropriate, reports critical incidents to the Food and Drug Administration (FDA) Adverse Event Reporting Program regarding (MedWatch, <http://www.fda.gov/medwatch/>; at 1-800-332-1088). Examples of reportable critical incidents include
- (i) Serious adverse events and medications errors
  - (ii) All types of deaths related to any drug

**(4) Community Relations and Education<sup>d</sup>**

For existing and/or new programs, to help minimize negative impact on the community, promote peaceful coexistence, and plan for change and program growth, programs develop and implement a general set of practices, policies, and procedures that

- (a) Consider community need and impact in selecting sites for programs
- (b) Elicit input from the community on the program's impact in the neighborhood
- (c) Ensure that the facility's physical appearance is clean and orderly and that the physical setting does not impede pedestrian or traffic flow
- (d) Identify community leaders for the purpose of fostering good community relations, and establish interpersonal contact and proactive associations with identified leaders (e.g., publicly elected representatives; local health, substance abuse, social, and/or human service agency directors; business organization leaders; community and health planning agency directors; grassroots community organization leaders; local police and law enforcement officials; and religious and spiritual leaders)
- (e) Develop and support a community relations plan, specific to the configuration and needs of the program within its community that includes the following steps:
  - (i) Establishing a liaison with community representatives to share information about the program, the community and mutual concerns and issues
  - (ii) Identifying program personnel who will function as community relations coordinators and define the goals and procedures of the community relations plan

- (iii) Serving as a community resource on substance abuse and related health and social issues, as well as promoting the benefit of medication-assisted treatment in preserving the public health
- (iv) Soliciting community input about medication-assisted treatment and the program's presence in the community
- (v) Developing program policies and procedures to effectively address or resolve community problems (including patient loitering and medication diversion), and ensuring that program operations do not affect community life adversely
- (f) Document community relations efforts and community contacts, evaluate these efforts and contacts over time, and address outstanding problems or deficiencies
- (g) Devise communication mechanisms so that interested parties and potential patients may obtain general information about the program outside regular operating hours

#### **(5) Voluntary and Involuntary Program Closure**

- (a) Programs develop a plan to establish, through State authorities or other governmental entities, procedures to ensure continuity of care for patients in the event of voluntary or involuntary closure of programs or individual medical practices. The plan includes steps for the orderly transfer of patients, records, and assets to other programs or practitioners.
- (b) Programs develop a plan to ensure that patient records from programs that are closing are secured and maintained for a specified period of time in accordance with State and Federal regulations.

42 CFR 8.12(c) (2) An OTP must maintain a current "Diversion Control Plan" or "DCP" as part of its quality assurance program that contains specific measures to reduce the possibility of diversion of controlled substances from legitimate treatment use and that assigns specific responsibility to the medical and administrative staff of the OTP for carrying out the diversion control measures and functions described in the DCP.

#### **D. Diversion Control**

Each program has a diversion control plan (DCP) that demonstrates accountability to its patients and to the community. The DCP also should demonstrate the efficient use of personnel and other resources to achieve the highest quality of patient care, while reducing possibilities for diversion of controlled substances from legitimate treatment to illicit use.

**Guidance:** DCPs should contain specific measures to reduce the possibility of diversion of controlled substances from legitimate treatment use and should assign specific responsibilities to the medical and administrative staff for implementation. The goal of this program responsibility is to reduce the scope and significance of diversion and its impact on communities. The DCP should contain a mechanism for periodic monitoring of clinical and administrative activities to reduce the risk of medication diversion. OTPs should also have a mechanism for problem identification and correction, as well as for prevention of related diversion problems.

A part of the DCP should be surveillance and monitoring of potential diversion and community problems, which may be associated with opioid agonist treatment. One of the goals of surveillance and monitoring is to answer the question, "Is there a diversion problem, and, if so, how does the clinic or the

community know?" For example, some OTPs may set up a system of rounds in which security or staff walks around the perimeter of the clinic on a regular and periodic basis to assess the activities at the entrances and in hallways, alleys, and the parking lot. This simple system of regularly checking the environment will help the program assess whether it has a loitering or diversion problem close to the treatment site. The clinic should examine its dosing and take-home dispensing practices to ensure that there are no potential weaknesses in the dispensing of medication that could lead to diversion problems. Another example of surveillance and monitoring involves consulting periodically with law enforcement in the community and in areas where patients live to discuss surveillance findings and the perceived and actual problems encountered.

It may be helpful to assign diversion problem identification, correction, and prevention functions to one of the OTP's committees, such as the quality assurance committee or the management committee. If the OTP is small, there may be only one committee for all staff and management business. In some OTPs, this is called "the committee of the whole."

OTPs should have a plan in place to address identified diversion problems. Several strategies may be helpful. Always investigate the alleged or actual source of diversion. If necessary, change the frequency of take-home reviews. Drug testing regimens may have to be reevaluated. Special, intensified groups or individual counseling sessions may be helpful for individuals or groups at risk for diversion problems. Patient committees to advise on policies, procedures, and problem solving may also help by giving patients a voice in keeping the treatment environment therapeutic and safe.

42 CFR 8.12(d) *Staff credentials*. Each person engaged in the treatment of opioid addiction must have sufficient education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. All physicians, nurses, and other licensed professional care providers, including addiction counselors, must comply with the credentialing requirements of their respective professions.

### **E. Professional Staff Credentials and Development<sup>e</sup>**

Each treatment program ensures the following:

- (1) Doctors, nurses, and other licensed professional care providers maintain current licenses and comply with the credentialing requirements of their own professions. Specific credentialing for work in addictions, by any formal body, is desirable, but not required.
- (2) Addictions counselors meet the qualifications outlined by the employing program and the State.
- (3) Before staff members provide care to patients, they receive initial education specific to the medication-assisted treatment used in the OTP and tailored to the patient populations served.
- (4) All staff members receive continuing education on opioid addiction treatment and related subjects. Staff may be qualified for their positions through training, education, and/or experience.
- (5) The OTP implements an individual annual training plan for each staff member.
- (6) The OTP develops detailed job descriptions for credentialed and noncredentialed staff. Job descriptions clearly define the qualifications and competencies needed to provide specific services.
- (7) Records of staff training events are kept and include the qualifications of educators, outlines of content, descriptions of methods, and rosters of attendees. OTPs maintain records of staff training events in personnel files.



- (8) Resources for problem solving and troubleshooting are accessible.
- (9) There are an adequate number of physicians, nurses, counselors, and other staff for the level of care provided, related to the number of patients enrolled in the program.

42 CFR 8.12(e) *Patient admission criteria*.—(1) Maintenance treatment. An OTP shall maintain current procedures designed to ensure that patients are admitted to maintenance treatment by qualified personnel who have determined, using accepted medical criteria such as those listed in the Diagnostic and Statistical Manual for Mental Disorders (DSM-IV), that the person is currently addicted to an opioid drug, and that the person became addicted at least 1 year before admission for treatment. In addition, a program physician shall ensure that each patient voluntarily chooses maintenance treatment and that all relevant facts concerning the use of the opioid drug are clearly and adequately explained to the patient, and that each patient provides informed written consent to treatment.

(2) Maintenance treatment for persons under age 18. A person under 18 years of age is required to have had two documented unsuccessful attempts at short-term detoxification or drug-free treatment within a 12-month period to be eligible for maintenance treatment. No person under 18 years of age may be admitted to maintenance treatment unless a parent, legal guardian, or responsible adult designated by the relevant State authority consents in writing to such treatment.

(3) Maintenance treatment admission exceptions. If clinically appropriate, the program physician may waive the requirement of a 1-year history of addiction under paragraph (e) (1) of this section, for patients released from penal institutions (within 6 months after release), for pregnant patients (program physician must certify pregnancy), and for previously treated patients (up to 2 years after discharge).

42 CFR § 8.2 *Opiate addiction* is defined as a cluster of cognitive, behavioral, and physiological symptoms in which the individual continues use of opiates despite significant opiate-induced problems. Opiate dependence is characterized by repeated self-administration that usually results in opiate tolerance, withdrawal symptoms, and compulsive drug taking. Dependence may occur with or without the physiological symptoms of tolerance and withdrawal.

## F. Patient Admission Criteria

### (1) Evidence of Current Physiological Dependence and Opioid Addiction

- (a) The program physician must diagnose addiction or dependence, document that diagnosis, and admit each patient to maintenance or detoxification treatment as medically necessary.

Criteria for admission should be based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision (DSM-IV-TR) (American Psychiatric Association [APA] 2000) definition of opioid dependence. Behavior supportive of a diagnosis of opioid dependence includes

- (i) Significant levels of tolerance resulting in withdrawal symptoms on abrupt discontinuation of opioid substances
- (ii) Signs and symptoms that reflect compulsive, prolonged self-administration of opioid substances that are used for no legitimate medical purpose or, if a general medical condition is present that requires opioid treatment, use of opioid doses that are greatly in excess of the amount needed for pain relief
- (iii) Such regular patterns of compulsive drug use that daily activities are typically planned around obtaining and administering opioids

- (iv) Purchase of opioids on the illegal market or obtaining opioids by faking or exaggerating general medical problems or by receiving simultaneous prescriptions from several physicians
- (v) Engaging in drug-related crimes, such as fraudulently writing prescriptions for opioids or diverting opioids prescribed for other patients or from pharmacy supplies (DSM-IV-TR) (APA 2000)

(2) Behavior indicative of opioid addiction includes

- (a) Continuing use of the opiate despite known adverse consequences to self, family, or society
- (b) Obtaining illicit opiates
- (c) Using prescribed opiates inappropriately
- (d) Previous attempt(s) at tapering methadone or other drugs

(3) Patients often exhibit the physical signs and symptoms of opioid dependence. Onsite (“point of collection”) test devices may be useful in screening a patient’s current physiological dependence.

(4) A 1-year history of addiction is necessary for admission to maintenance treatment. The absence of current physiological dependence should not be an exclusion criterion, and admission is clinically justified. OTPs can accept arrest and medical records, information from significant others and relatives, and other information to document the 1-year history of addiction.

(5) Finally, there may be individuals in special populations who have a history of opioid use, but who are not currently physiologically dependent. These populations include persons recently released from a penal institution; pregnant patients; previously treated patients—as listed above in the regulation—or persons recently discharged from a chronic care facility. Federal regulations waive the 1-year history of addiction for these special populations because individuals in these populations are susceptible to relapse to opioid addiction leading to high-risk behaviors with potentially life-threatening consequences.

(6) A physician assesses each patient before admission to medication-assisted treatment. The exceptional circumstance is that the physician may review the medical examination performed by another qualified health professional by phone or fax, make the required diagnosis, and admit the patient. The physician would then review and countersign the patient record within 72 hours. Standing orders for admitting patients are not acceptable.<sup>f</sup>

## G. Informed Consent

Each treatment program

- (1) Obtains voluntary, written, program-specific informed consent to treatment from each patient at admission.
- (2) Informs each patient about all treatment procedures, services, and other policies and regulations throughout the course of treatment.
- (3) Before medicating the patient, obtains voluntary, written, informed consent from each patient to the specific pharmacotherapy ordered by the physician.

- (4) Informs each patient of the following:
- (a) That the goal of medication-assisted treatment is stabilization of functioning.
  - (b) That, at periodic intervals, in full consultation with the patient, the provider discusses present level of functioning, course of treatment, and future goals. These discussions should not place an unfair burden or pressure on the patient to withdraw from medication or to remain on medication maintenance unless medically indicated.
- (5) Informs each patient, at admission, about State-specific requirements and program policies regarding the report of suspected child abuse and neglect, as well as other forms of abuse (e.g., violence against women).
- (6) Adheres to all requirements of the Federal confidentiality regulations (42 CFR Part 2) and HIPAA (45 CFR Part 160 and Subparts A and E of Part 164).
- (7) Promulgates and makes available a written description of patients' rights and responsibilities.

42 CFR 8.12(f) *Required services*.—(1) General. OTPs shall provide adequate medical, counseling, vocational, educational, and other assessment and treatment services. These services must be available at the primary facility, except where the program sponsor has entered into a formal, documented agreement with a private or public agency, organization, practitioner, or institution to provide these services to patients enrolled in the OTP. The program sponsor, in any event, must be able to document that these services are fully and reasonably available to patients.

(2) Initial medical examination services. OTPs shall require each patient to undergo a complete, fully documented physical evaluation by a program physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician, before admission to the OTP. The full medical examination, including the results of serology and other tests, must be completed within 14 days following admission.

## H. Patient Medical and Psychosocial Assessment

The purpose of an assessment is to determine treatment eligibility, develop a treatment plan, and establish a measure for the response to treatment. For all applicants initially deemed eligible for medication-assisted treatment, program staff members complete a comprehensive physical examination, laboratory workup as indicated, psychosocial assessment, preliminary treatment plan, and patient orientation during the initial treatment stage.

### (1) Screening, Assessment, and Evaluation<sup>g</sup>

“Screening” is the process of determining whether large groups of people have certain risk factors associated with a substance abuse disorder, and referring appropriate candidates for further assessment. When conducting an individual screening, if the clinician determines that one or more risk factors are present, then the patient should receive an assessment for admission to treatment or be referred elsewhere for follow-up. Screening usually involves the use of one or more standardized techniques, such as a questionnaire or a structured interview. Screening may include observation of known presenting complaints and symptoms that are indicators of substance use disorders. Screening involves triage, a clinical determination to decide whether the patient is sufficiently physically and mentally stable to undergo assessment and treatment safely at the screening location (CSAT 2005, p. 293). If professional staff members identify a patient who is medically or mentally

unstable or at risk for imminent harm to himself or herself or others, then staff should arrange appropriate transfer to the required type and level of care.

“Assessment” is the process of identifying the precise nature and extent of a patient’s substance use disorder and other medical, mental health, and social problems, as a basis for treatment planning. Assessment usually begins during program admission and continues throughout treatment. It includes completing a personal substance abuse history, physical examination, laboratory evaluation, and determination of disease morbidity. Often, professional staff may further assess the severity of disease in terms of physiologic dependence, organ system damage, and psychosocial morbidity. Assessment also may involve determining patient motivation and readiness for change. (CSAT 2005, p. 284).

“Evaluation” is the close examination or appraisal of a patient’s health, including the patient’s physical and mental capacity and potential.

- (a) A patient who is being admitted to treatment should receive intensive evaluations, including a medical and health history and physical examination, to determine initial dosage and to place the patient into the appropriate level of treatment. Collecting a health history and determining the length of drug dependence is helpful for appropriately placing the patient and to identify other chronic or acute medical conditions that need to be addressed. Upon completion of proper patient consent, the program should seek medical records from other health care providers.
- (b) Each program
  - (i) Determines current physical dependence and addiction. Staff members take a history, conduct an examination, and perform screening to determine the patient’s current degree of dependence on narcotics and, to the extent possible, the length of time the patient has been dependent on opioids. This assessment includes a physical examination for the presence of clinical signs of addiction, such as old and fresh needle marks, constricted or dilated pupils, and/or an eroded or perforated nasal septum, and a state of sedation or withdrawal. The examination evaluates the observable and reported presence of withdrawal signs and symptoms, such as yawning, rhinorrhea, lacrimation, chills, restlessness, irritability, perspiration, piloerection, nausea, and diarrhea.
  - (ii) Assesses the impact of induction onto the treatment drug. Methadone has well documented impacts on several organ systems, including the respiratory, nervous, liver, and cardiac systems. Therefore, the medical exam should consider whether the treatment drug will be methadone, buprenorphine, or another medication, or whether the treatment indicated is induction, detoxification, or maintenance. This assessment should occur upon entry into the program and includes documenting a list of medications the patient is currently taking with the actual (rather than prescribed) doses, any diverted or illicit substances the patient is taking, potential adulterants sometimes contained within illicit substances that are in themselves medically active (e.g., quinine), and medically active over-the-counter (OTC) or natural remedies. The physician should check on and consider interactions between these medications and the medication ordered to treat opioid addiction prior to initiating treatment.

For example, many medications can act to increase the QT interval seen on an electrocardiogram (EKG) and potentially lead to torsades de pointes, a potentially life-threatening cardiac arrhythmia. Physicians should be particularly aware of potential QT-prolonging effects of methadone, especially with high doses. In addition, physicians

should be aware of interactions between methadone and other medications that also have QT-prolonging properties, or with medications that slow the elimination of methadone (CSAT 2005, p. 35). The medical assessment should specifically cover the symptoms and risk factors for torsades de pointes, and any indicated follow-up tests that may include an EKG or a more comprehensive electrophysiological assessment. The treatment plan should also address concerns related to the discovery or risk of torsades de pointes.

- (iii) Documents medical and family history, including sex and age of children, whether children are living with parents, and family medical and drug use histories. A complete medical history is documented, and includes current information to determine chronic or acute medical conditions, such as diabetes; renal diseases; hepatitis A, B, C, and D; HIV exposure; tuberculosis (TB); sexually transmitted diseases (STDs); other infectious diseases; sickle-cell trait or anemia; pregnancy (including past history of pregnancy and current involvement in prenatal care); and chronic cardiopulmonary diseases. Programs complete a full medical evaluation within 14 days of treatment initiation.
- (iv) Completes a psychiatric history and mental status examination with DSM-IV-TR (APA 2000) categorization.
- (v) Conducts a comprehensive evaluation conducted by one or more disciplines that include the medical, psychosocial, vocational, educational, behavioral, family, financial, legal, health, and self-care needs of the patient. This evaluation should be conducted within approximately 30 days of admission to treatment or earlier when necessary. The program completes assessment updates and treatment plan updates quarterly for the first year of continuous treatment. In subsequent years, the OTP updates assessments and treatment plans semiannually.
- (vi) Triage and refers patients who have the need for services not provided by the OTP to other care providers, as appropriate.
- (vii) For patients referred elsewhere, ensures that the exchange of information conforms to confidentiality regulations for patients in drug or alcohol treatment (42 CFR Part 2) and HIPAA regulations (45 CFR Part 160 and Subparts A and E of Part 164).

## **(2) Medical Laboratory Evaluation/Diagnostic Criteria**

Based on an individual's history and physical examination, programs evaluate the possibility of infectious disease, liver or pulmonary conditions, cardiac abnormalities, psychiatric problems, dermatologic sequelae of addiction, and possible concurrent surgical and other problems by conducting testing or referring patients for consultation and testing. Not all assessments, screenings, and diagnostic evaluations need to be done within the program itself. It may be more appropriate to case manage the array of evaluations needed through a network of qualified and cooperating agencies and consultants. The program should have appropriate information-sharing agreements with these other providers, in accordance with Federal regulations. Patients referred for outside services should have access to nearby providers to facilitate better care for patients and to avoid additional travel and inconvenience.

**(a)** Recommended tests and assessments, as medically appropriate, include the following:

- (i)** Vital signs, including blood pressure, pulse, respirations, and temperature

- (ii) TB skin test and chest x ray, if skin test is positive (including consideration for allergy)
  - (iii) Screening test for syphilis
  - (iv) Complete blood count (CBC) and lipid panel
  - (v) Electrocardiogram (EKG), chest x ray, Pap smear, and screening for sickle cell disease
  - (vi) Liver function tests and viral hepatitis marker tests
  - (vii) HIV testing and counseling
  - (viii) Tests appropriate for the screening or confirmation of illnesses or conditions, as recommended by U.S. Preventive Services Task Force or based on concerns specific to the patient regarding renal function, electrolyte imbalance, metabolic syndromes, pain, and so forth
  - (ix) Pregnancy test when indicated
  - (x) Appropriate neurological or psychological testing and assessment, as indicated
  - (xi) Based on baseline screening tests, appropriate referral for more diagnostic testing, especially when those results have potential to significantly change treatment decisions (such as when a screening EKG suggests a prolonged QT interval in a symptomatic patient)
- (b) Programs conduct an initial toxicology test as part of the admission process. Programs test admission samples for opiates, methadone, amphetamines, cocaine, marijuana, and benzodiazepines, at the minimum. Individual patient need and local drug-using conditions and trends determine additional testing.
- (c) Other considerations include the following:
- (i) Financial problems, transportation to referral sites, stress, and poor mental and physical well-being may be barriers to comprehensive laboratory testing on admission. Other tests may be deferred until the patient has stabilized.
  - (ii) Patients may also require other health care. Programs without primary care onsite should refer patients for laboratory tests and follow up on results. The optimal deadline for completing needed health-related procedures is 3 months after admission.

42 CFR § 8.12(f) (3) *Special services for pregnant patients.* OTPs must maintain current policies and procedures that reflect the special needs of patients who are pregnant. Prenatal care and other gender specific services or pregnant patients must be provided either by the OTP or by referral to appropriate healthcare providers.

### I. Pregnant and Postpartum Patients<sup>h</sup>

**NOTE: Although promising, the level of evidence supporting buprenorphine maintenance during pregnancy is not as compelling as the evidence supporting methadone maintenance for pregnant women. As of this writing, both methadone and buprenorphine are Pregnancy Category C drugs,**

**which call for a careful risk/benefit analysis, but for which there is no known harm to the human fetus when medication is taken as directed and relapse is avoided.**

- (1) The treatment program gives priority to pregnant women who seek treatment and documents on an intake log or in other accessible program records the reasons for denying admission to any pregnant applicant.
- (2) The treatment program ensures that every pregnant patient has the opportunity for prenatal care, provided onsite or by referral to appropriate health care providers. If the treatment program refers the patient elsewhere for prenatal care, there are agreements in place, including informed consent procedures, which ensure reciprocity in the exchange of pertinent clinical information regarding compliance with the recommended course of medical care.
- (3) If appropriate prenatal care is not available onsite or by referral, or if the pregnant patient cannot afford care or refuses prenatal care services, the treatment program, at a minimum, offers her basic prenatal instruction on maternal, physical, and dietary care as part of the counseling services and documents the provision of these services in the clinical record.
- (4) If a pregnant patient refuses direct prenatal services or appropriate referral for such care, the treating physician in the treatment program may use informed consent procedures to have the patient formally acknowledge, in writing, that the program offered these services but the patient refused them.
- (5) For pregnant women in methadone treatment, the program
  - (a) Maintains patients who become pregnant during treatment on the pre-pregnancy dosage, if effective, and applies the same dosing principles as used with any other non-pregnant patient.
  - (b) Ensures that the initial methadone dose for a newly admitted pregnant patient and the subsequent induction and maintenance dosing strategy reflect the same effective dosing protocols used for all other patients.
  - (c) Monitors the methadone dose carefully, especially during the third trimester when pregnancy-induced changes in the rate at which methadone is metabolized or eliminated from the system may necessitate either an increased or a split dose.
  - (d) In general, detoxification during pregnancy is not recommended or considered the best practice. If a pregnant patient elects to withdraw from methadone and stays in the program, a physician experienced in addiction medicine supervises the withdrawal process with regular fetal assessments, as appropriate, for gestational age, as part of the withdrawal process. The physician should not initiate withdrawal before 14 weeks' or after 32 weeks' gestation.
- (6) The program supports the decision to breast-feed during methadone treatment, unless medically contraindicated, for example, by the presence of HIV or HTLV I or II infection in the mother. The treatment program should document appropriate counseling and informed decisionmaking between provider and patient to ensure that issues mentioned in the latest patient information sheets and product inserts for methadone are covered and understood.
- (7) The treatment program establishes and implements policies and procedures, including informed consent, to ensure appropriate follow-up and primary care for the new mother and well-baby care for the infant. Informed consent refers to the patient's agreement to receive treatment as well as agreement to release information to and obtain information from pertinent health care providers.

- (8) If a pregnant patient is discharged, the program should identify the physician to whom the person served is being discharged. The program staff records the name, address, and telephone number of the physician who will be caring for the patient after discharge.

### **J. Concurrent Pregnancy and HIV Infection**

- (1) Pregnant women in methadone treatment with concurrent HIV infection are subject to the same policies and procedures established for all HIV-infected patients in treatment and receive the same services.
- (2) Treatment programs offer pregnant patients with HIV diagnoses the same treatment opportunities and services, directly or by referral, as HIV-diagnosed patients who are not pregnant.
- (3) Treatment programs ensure that all pregnant patients with concurrent HIV infection are (1) informed that HIV medication treatment is currently recommended to reduce perinatal transmission and (2) provided with appropriate referrals and case management for this treatment.

### **K. Neonatal Abstinence Syndrome**

Infants prenatally exposed to opioids may experience neonatal abstinence syndrome, characterized by hyperactivity of the central and autonomic nervous systems reflected in changes in the gastrointestinal tract and respiratory system. Withdrawal symptoms may begin at any time from minutes or hours after birth to 2 weeks later, but most appear within 72 hours. Infants with this syndrome may engage in frantic sucking behaviors, but they may have difficulty feeding because their sucking reflex is uncoordinated.

Programs ensure that mothers who have infants who may be susceptible to neonatal abstinence syndrome seek comprehensive evaluation and treatment for the infant. A medical evaluation is important because various other conditions may mimic neonatal abstinence syndrome, such as hypoglycemia, sepsis, and neurological illnesses. Treatment may include pharmacological management in accordance with current clinical practice guidelines and best medical practice (CSAT 2005, pp. 218–219).

42 CFR § 8.12 (f) (4) *Initial and periodic assessment services.* Each patient accepted for treatment at an OTP shall be assessed initially and periodically by qualified personnel to determine the most appropriate combination of services and treatment. The initial assessment must include preparation of a treatment plan that includes the patient's short-term goals and the tasks the patient must perform to complete the short-term goals; the patient's requirements for education, vocational rehabilitation, and employment; and the medical, psycho-social, economic, legal, or other supportive services that a patient needs. The treatment plan also must identify the frequency with which these services are to be provided. The plan must be reviewed and updated to reflect that patient's personal history, his or her current needs for medical, social, and psychological services, and his or her current needs for education, vocational rehabilitation, and employment services.

### **L. Treatment Planning, Evaluation of Patient Progress in Treatment, and Continuous Clinical Assessment**

#### **(1) Treatment Considerations Related to the Natural History of the Disease**

The clinical assessment of all patients should take into account the natural history of opioid addiction as altered by time and treatment. Patients normally proceed from one stage of treatment to the next or move back and forth among the naturally occurring stages. Treatment tasks are determined in relation to the patient's stage in recovery.



The stages of medication-assisted treatment are listed below. It is important at all stages that psychosocial treatment, as well as medical treatment, be of sufficient intensity and duration to be effective.

- (a) Initial treatment: consisting of intensive assessment and intervention, from 3 to 7 days in duration.
- (b) Early stabilization: from the 3rd to 7th day of treatment through 8 weeks.
- (c) Long-term treatment: from the end of early stabilization for an indefinite period, either in a program setting or in an office-based setting.
- (d) Medically supervised withdrawal with continuing care, if and when appropriate.
- (e) Immediate emergency treatment: provision of medication-assisted treatment in situations in which access to a comprehensive treatment program is not feasible (e.g., emergency room, detention center, inpatient hospital unit, or other health care settings outside of certified OTPs) or for conditions such as pregnancy, HIV-spectrum disease, or other illnesses and psychiatric problems.
- (f) Findings from the initial medical assessment should be reassessed should there be any noted changes in the patient's physical condition or should the patient develop symptoms consistent with adverse events related to specific opioid medication treatment (e.g., developing symptoms consistent with torsades de pointes). Additionally, if there is any change in medication or other drug use documented in the initial and subsequent medical exams, then the clinical staff should pay specific attention to potential medication interactions.

The patient's response to treatment determines her or his progression through the stages of treatment. Some patients may remain in one stage for a considerable period, while, in contrast, others may progress very quickly. It is not uncommon for a patient to relapse. There is both an individual and a public health advantage to maintaining a patient on medication, even when psychosocial treatment may not be yielding optimum results.

Pharmacotherapy may benefit the individual patient even when he or she does not appear to be benefiting from other clinic services. Additionally, pharmacotherapy may benefit the patient who no longer needs ancillary services.

## **(2) Intensity and Duration of Treatment**

- (a) In general, a greater intensity of services is desirable at the beginning of treatment and when staff members identify a patient's relapse or when relapse "trigger" conditions exist.
- (b) Many patients often need psychosocial services for an extended period because of the multiplicity of their problems.
- (c) For long-term opiate addiction treatment, many patients need continuing medication, with or without psychosocial services, as outlined in TIP 43, "Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs" (CSAT 2005).
- (d) There are no limits on the duration or the dosage level of medication, unless clinically indicated. Likewise, there are no limitations on psychosocial services offered even when patients are receiving "0" dose levels.

**(3) Retention in Treatment<sup>i</sup>**

- (a) Programs and individual practitioners make every effort to retain patients in treatment as long as clinically appropriate, medically necessary, and acceptable to the patient.
- (b) The treatment program takes appropriate therapeutic measures to address the other problems identified in the treatment plan.

**(4) Voluntary Patient Relocations, Program Transfers, and “Guest Dosing”**

When a patient relocates, transfers to another treatment program, or needs temporary care at another program (“guest dosing”), the original treatment program ensures that the patient makes a smooth transition, and the program attempts to avoid breaks in treatment that could lead to relapse.

The original treatment program should forward relevant medical records to the receiving treatment program, with patient consent in accordance with the privacy standards of 42 CFR 2.

**(5) Relapse Prevention**

- (a) Psychosocial treatment continues for patients electing to discontinue pharmacotherapy.
- (b) If possible, clinics and individual practitioners track patients and reinstitute pharmacotherapy at the first sign of relapse or impending relapse. (See N. (3), “Support of Medically Supervised Withdrawal.”)
- (c) Some patients progress into long-term pharmacotherapy and no longer need psychosocial services. If the need for psychosocial services reemerges, however, programs provide the opportunity to return to full services.

42 CFR 8.12(e) (4) *Detoxification treatment*. An OTP shall maintain current procedures that are designed to ensure that patients are admitted to short- or long-term detoxification treatment by qualified personnel, such as a program physician, who determines that such treatment is appropriate for the specific patient by applying established diagnostic criteria. Patients with two or more unsuccessful detoxification episodes within a 12-month period must be assessed by the OTP physician for other forms of treatment. A program shall not admit a patient for more than two detoxification treatment episodes in 1 year.

**M. Detoxification, Tapering, or Medically Supervised Withdrawal<sup>j</sup>**

As clinically appropriate, a physician may admit a patient to an OTP for “detoxification” treatment, hereinafter referred to as “medically supervised withdrawal.” “Medically supervised withdrawal” refers to a gradual reduction, or tapering, of the medication dosage over time under the supervision of a physician, to achieve the elimination of tolerance and physical dependence to opioid medications. “Tapering” is also a synonym for these terms. “Detoxification” is a legal and regulatory term that has fallen into disfavor with the medical community; some experts view “detoxification” as a misnomer because drugs used to treat addiction are not toxic when administered in proper dosages.

**N. Medically Supervised Withdrawal From Medication<sup>k</sup>**

(1) Medically supervised withdrawal is conducted

- (a) As a voluntary and therapeutic process, agreed on by physician and patient or

- (b) In response to the request of the patient—against the advice of the physician, counselor, and other staff—that is, against medical advice (AMA).
- (2) The physician initiates voluntary supervised withdrawal from medication-assisted treatment in collaboration with and at the request of the rehabilitated patient. Voluntary supervised withdrawal is completely different and distinct from involuntary tapering or administrative withdrawal or other types of medically supervised withdrawal.
- (a) In initiating medically supervised withdrawal, the physician reduces dosages of medication at a rate well tolerated by the patient and in accordance with sound clinical judgment. For example, the physician decreases a dose by 1 to 2.5 mg per day for inpatients and 2.5 to 10 mg per week for outpatients.
  - (b) For women of childbearing potential, the physician conducts an assessment for pregnancy and reviews the results of a pregnancy test before initiating medically supervised withdrawal. (See 2. I. (5) (d)—The physician should not initiate withdrawal before 14 weeks’ or after 32 weeks’ gestation.)
  - (c) The OTP resumes medication-assisted treatment if the patient experiences impending or actual relapse.

### **(3) Support of Medically Supervised Withdrawal**

The following program policies and procedures promote successful medically supervised withdrawal, whether conducted with or against medical advice:

- (a) A variety of supportive options is available to improve chances of a successful episode of medically supervised withdrawal.
- (b) Increased counseling is available prior to discharge.
- (c) Participants are encouraged to attend a 12-step or other mutual-help program that is sensitive to the needs of patients receiving medication-assisted treatment.

### **(4) Additional Considerations for Medically Supervised Withdrawal Against Medical Advice**

- (a) The patient has the right to leave treatment when he or she chooses to do so. The program explains the risks of leaving treatment and offers information about or referral to alternative treatment options.
- (b) In the case of a patient who leaves a program abruptly, the program may readmit the patient within 30 days without repeating the initial assessment procedure required by regulation 42 CFR § 8.
- (c) The program documents the issue that caused the patient to seek discharge and provides full documentation of steps taken to avoid discharge.
- (d) If medically supervised withdrawal fails, the physician considers initiating maintenance treatment.
- (e) In the case of a pregnant patient, the program keeps the physician or agency following the patient for prenatal care informed, consistent with privacy standards of 42 CFR 2.

## O. Administrative Withdrawal and Discharge

A major goal for programs is to retain patients for as long as they can benefit from treatment and express a desire to continue it. Because retaining the patient is not always possible, programs provide procedures for administrative withdrawal that employ the principles involved in medically supervised withdrawal from medication. Administrative withdrawal is usually involuntary. When a program makes the decision administratively to discharge a patient from pharmacotherapy, the program offers a humane schedule of medically supervised withdrawal, using sound clinical judgment. A suggested medically supervised withdrawal schedule for administrative withdrawal is generally a minimum of 30 days, but the physician may adjust this timeframe depending on clinical factors. The program documents the person's condition during medically supervised withdrawal in the patient's record. On discharge, the program makes appropriate alternative referrals. Given the short timeframe and poor prognosis for the withdrawal procedure, patient referral or transfer to a suitable alternative treatment program is the preferred approach.

- (1) Administrative withdrawal may result from
  - (a) Nonpayment of fees. Remedies may include referral to a more affordable treatment program. As a last resort, programs provide a humane schedule of medically supervised withdrawal.
  - (b) Disruptive conduct or behavior. Such behaviors may have an adverse effect on the program, staff, or patient population of such gravity as to justify the involuntary medically supervised withdrawal and discharge of a patient, despite an extremely poor prognosis. Disruptive behaviors include violence, direct threat of violence, dealing drugs, repeated loitering, and flagrant noncompliance, resulting in an observable, negative impact on the program, staff, and other patients. Patients who exhibit disruptive behaviors should receive a mental health evaluation and referral, as appropriate, prior to administrative withdrawal.
  - (c) Incarceration or other confinement.
- (2) The OTP takes into consideration all factors affecting the patient on a case-by-case basis, and documents procedures for any involuntary terminations of patients.
- (3) Efforts made regarding referral or transfer of the patient to a suitable alternative treatment program should be documented.
- (4) The program makes specific efforts to ensure referrals are followed through to completion for the pregnant patient in the rare event the patient is administratively withdrawn and discharged. Provider(s) should carefully follow up with both patient's pregnancy and opioid dependency. It may be helpful for the program to establish prearranged agreements for treatment for this very purpose.

## P. Continuing Care

- (1) An essential part of treatment is continuing care that includes discharge planning and relapse prevention.
- (2) Continuing care also includes procedures that address patients' physical and mental health problems following medically supervised withdrawal. For example, the program addresses the need for counseling and appropriate medication to help with sleep disorders, depression, and other problems.

- (3) The treatment program provides for continuing care following the last dose of medication, including making a referral for continuing outpatient care and planning for reentry to maintenance treatment if relapse occurs.

## **Q. Additional Treatment Planning Considerations**

### **(1) Management of Co-Occurring Disorders**

When possible and appropriate, co-occurring disorders are concurrently managed onsite. This includes management of multiple drug use problems, as well as psychiatric and medical disorders. Coexisting conditions, especially in patients from disenfranchised populations, are most effectively treated at a single site. It is most critical that the treatment provider has an understanding of both the substance use and co-occurring disorder. If the appropriate level of expertise is not available within the program, then staff members arrange for the patient to receive appropriate care elsewhere. Consideration should be given to limit barriers to treatment, e.g., financial and transportation burdens and time to and from care.

### **(2) Alcohol and Other Drug Abuse**

- (a) Programs manage concurrent abuse of other drugs within the context of the medication-assisted treatment, following principles described in TIP 43, “Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs” (CSAT 2005).
- (b) Program staff members are knowledgeable about current effective strategies for treating alcohol, cocaine, and other drug abuse.
- (c) Ongoing multidrug abuse is not necessarily a reason for discharge. Patients engaging in such multidrug use receive careful evaluations to determine the most therapeutic course of treatment, in light of the fact that many patients (and communities) continue to benefit from medication-assisted treatment even when the patients are not fully abstinent from all drugs of abuse. The treatment decision for poly-drug-abusing patients should take into account the patient’s condition and the treatment team’s best clinical judgment. Treatment programs coordinate care with providers outside the OTP who prescribe medication with abuse potential.

### **(3) Care of Patients With Mental Health Needs**

Treatment programs

- (a) Ensure that patients with mental health needs are identified through the assessment process and referred to appropriate treatment.
- (b) Ensure that patients are monitored during withdrawal and/or discharge for emergence of symptoms of mental illness.
- (c) Establish and use linkages with mental health providers in the community.
- (d) Establish a mechanism to evaluate mental health medication jointly with the mental health provider. If possible and if indicated, programs may even dispense such medications in conjunction with the daily dose of opioid medication.

**(4) HIV Testing and Care of HIV-Positive Patients**

- (a) Programs develop and implement a plan for educating patients about HIV/AIDS, testing procedures, confidentiality, reporting, followup care, counseling, safer sex, social responsibilities, universal precautions, and sharing of intravenous equipment.
- (b) Programs offer people living with HIV/AIDS options to promote maximum benefits of medication-assisted treatment during the course of HIV/AIDS treatment, including addressing medication side effects and toxicity.
- (c) Programs establish and utilize linkages with community HIV/AIDS treatment programs, social support services, and other HIV/AIDS prevention programs. These linkages should facilitate systems that continue opioid medication for debilitated patients and may include collaboration or transfer of care to primary physicians when AIDS becomes the primary health concern. Programs arrange confidential information exchange—consistent with 42 CFR 2—to ensure that appropriate information reaches the providers caring for the patient.
- (d) The treatment program and the provider responsible for HIV/AIDS medication management work together to monitor and case manage medication adherence and adverse events.

**(5) Treatment Considerations for Viral Hepatitis**

- (a) Patients who test positive for viral hepatitis receive a referral for further evaluation and treatment, if necessary. Patients who test negative are immunized against hepatitis A and B, as appropriate, and against other viral hepatitis strains as those vaccines become available.
- (b) Staff should receive education about all forms of viral hepatitis and their effects on the health of the patient and engage in patient teaching on these subjects. Staff and patient education about hepatitis C is especially important, because it is the most common blood borne virus among intravenous drug users. Staff and patients should also be educated regarding the prevention of all forms of viral hepatitis, and the treatments for hepatitis, especially as they may affect the mental health of the patient and dosage levels of opioid medications.
- (c) Many patients identified as positive for hepatitis C virus (HCV) may benefit from antiviral therapy. The treatment program and the agency responsible for HCV and any other viral hepatitis medications should work together to monitor and case manage medication adherence and adverse events. Information exchanges, with patient agreement consistent with 42 CFR 2, ensure that appropriate information reaches the providers caring for the patient.

**(6) Treatment Considerations for Smoking Cessation**

Treatment programs address smoking and tobacco cessation with patients as an integral part of their treatment.

**(7) Co-Occurring Pain Patients<sup>1</sup>****(a) Pain Management in Maintenance Patients**

- (i) For the patient in medication-assisted treatment, management of chronic pain may include referral for consultation with a specialist in pain medicine, when possible and appropriate.

**(ii) Management of acute pain entails**

- Continuing the regularly scheduled dose of medication and
- Additionally prescribing adequate doses of appropriate pain medications, including short-acting opioid medications.

**(b) Other Principles of Pain Management**

- (i) Treatment programs make careful diagnostic distinctions between the physical dependence associated with chronic administration of opioids for relief of pain and the disease of opioid addiction. Apparent drug-seeking behaviors, typically associated with the disease of chronic opioid addiction, may occur as a response to inadequately treated or prolonged pain. This phenomenon is often referred to as “pseudo-addiction.”
- (ii) Generally, patients are not admitted to medication-assisted treatment to receive opioids only for pain, but there are exceptions to this principle especially if no pain treatment settings are available in the community.
- (iii) Patients with both chronic pain disorder and addiction should receive treatment from pain and addiction medicine specialists employing a multidisciplinary-team approach. The site of such treatment may be either a medical clinic or an OTP, depending on the patient’s need and the best utilization of available resources.
- (iv) Patients who are diagnosed with physical dependence and a pain disorder are not prohibited from receiving medication-assisted treatment for either maintenance or medically supervised withdrawal in an OTP setting. Similarly, addiction patients in medication-assisted treatment may receive both medication-assisted treatment and adequate doses of opioid analgesics for pain; the regulations and treatment guidelines permit administering both when medically necessary.

**(8) Cultural Competency**

- (a) Programs develop and implement written nondiscrimination policies to ensure equal access to treatment for all persons in need, regardless of race, ethnicity, gender, disability, age (with specific reference to policies for minors), or sexual orientation.
- (b) Programs are sensitive to the culture and values of patients in treatment.
- (c) Programs ensure that persons in positions of authority are professionally and culturally competent. For example, program leadership should be able to work effectively with the local community and/or receive input from members of minorities or from advisers knowledgeable of gender, ethnicity, and language issues.
- (d) Print materials, electronic media, and course offerings employ unbiased and nonstigmatizing language.
- (e) As appropriate, programs offer treatment for groups organized with special needs in mind (e.g., gender, sexual minority, seniors, and Spanish language).

**(9) Care of Adolescents in Treatment**

- (a) Programs tailor assessments to the developmental stage of the patient.

- (b) Programs develop and implement policies to ensure that adolescents are not harassed or exploited by older patients or staff.

**(10) Criminal Justice Issues**

- (a) Programs develop procedures to coordinate with agents of the criminal justice system on behalf of patients.
- (b) Programs communicate and cooperate with the criminal justice system in a way that advocates for continuous treatment of incarcerated patients, as well as those on probation or parole.

**(11) General Principles Regarding Care of Women in Treatment**

- (a) The policies and procedures of each treatment program reflect the specific needs of female patients.
- (b) Treatment programs make provisions to provide respectful and safe treatment of women.
- (c) The use of physical space, including restrooms, reflects the special needs of female patients.
- (d) All staff members receive intensive training in the specific characteristics and needs of women participating in their particular treatment program.
- (e) Program policies ensure appropriate clinical flexibility in assigning female patients to counselors who are sensitive to and trained to address their individual needs (e.g., domestic violence, sexual abuse).
- (f) Program policies and procedures ensure that the option of single-sex groups is available to all patients, as needed.

**(12) Family Needs**

- (a) Treatment programs provide opportunities for involvement of family and significant others in therapy.<sup>m</sup>
- (b) Treatment programs offer onsite education and training for all male and female parenting patients, or refer patients to appropriate parenting skills services, and make referrals for appropriate childcare services.
- (c) Program services include reproductive health education for all patients and appropriate referrals, as needed, for contraceptive services.
- (d) Children of patients in medication-assisted treatment may have special mental health and cognitive needs, especially if there has been physical or sexual abuse or neglect. Treatment programs offer referrals to appropriate resources and/or parenting support groups (CSAT 2005).

**(13) Alternative Therapies**

Programs support patient choice in seeking alternative therapies while providing appropriate guidance in the process. Programs may provide culturally appropriate or popular and nonharmful



alternative therapies as indicated (e.g., providing a space for sweat lodge ceremonies in a rural clinic serving Native Americans, or offering acupuncture).

#### **(14) Treatment of Other Diseases and Conditions of Public Health Interest**

- (a) Programs should treat patients diagnosed with disorders that require reporting to public health departments or refer those patients for further evaluation and treatment elsewhere. Examples of these types of diseases include TB and STDs. Programs should ensure that each patient has access to low-cost or free immunizations recommended by the CDC.
- (b) Staff members should become knowledgeable about existing and emerging diseases of a public health interest and educate patients about these conditions. Treatment programs are continually prepared to review and modify clinical approaches—and to address related mental health issues for patients and staff—as the public health environment changes.
- (c) Programs exchange information appropriately with the providers and health departments caring for the patients with reportable diseases or conditions, taking into account informed patient consent consistent with 42 CFR 2.

42 CFR § 8.12(f) (5) *Counseling services*. (i) OTPs must provide adequate substance abuse counseling to each patient as clinically necessary. This counseling shall be provided by a program counselor, qualified by education, training, or experience to assess the psychological and sociological background of patients, to contribute to the appropriate treatment plan for the patient and to monitor patient progress.

(ii) OTPs must provide counseling on preventing exposure to, and the transmission of, human immunodeficiency virus (HIV) disease for each patient admitted or readmitted to maintenance or detoxification treatment.

(iii) OTPs must provide directly, or through referral to adequate and reasonably accessible community resources, vocational rehabilitation, education, and employment services for patients either who request such services or who have been determined by the program staff to be in need of such services.

### **R. Concurrent Services**

#### **(1) Orientation to Treatment<sup>n</sup>**

Patients receive orientation to treatment initially and receive ongoing education about

- (a) Signs and symptoms of overdose and when to seek emergency assistance
- (b) The medication they are taking, including side effects and common myths about the medication or modality of treatment
- (c) The nature of addictive disorders
- (d) The benefits of treatment and nature of the recovery process, including phases of treatment
- (e) Clinic guidelines, rules, and regulations, including the requirement to sign a formal agreement of informed consent, and fees and billing procedures
- (f) Noncompliance and discharge procedures, including administrative withdrawal from medication

- (g) Patient's rights
- (h) Confidentiality and how release of information is permitted in accordance with 42 CFR Part 2
- (i) Toxicology testing procedures
- (j) Dispensing medication
- (k) HIV-spectrum and other infectious diseases
- (l) Potential drug interactions
- (m) Agreements needed to exchange appropriate information within the network of consultants and referral agencies in accordance with HIPAA Regulations and 42 CFR Part 2.

## **(2) Substance Abuse Counseling**

Appropriately trained, experienced, and qualified substance abuse counselors provide services of the intensity and duration required to meet the individual needs of the patient population. Programs determine staffing patterns by taking into account the characteristics and needs of particular patient populations. Likewise, patient-to-staff ratios are sufficient to ensure that patients have reasonable and prompt access to counselors, and to provide the required frequency and intensity of counseling services.

## **(3) Twelve-Step or Other Mutual-Help Groups**

The use of 12-step or other mutual-help groups should be encouraged. Sometimes these groups are unfamiliar with opioid addiction treatment. OTPs can establish their own 12-step or other mutual-help programs and should identify those groups that are accepting of maintenance pharmacotherapy.

## **(4) Counseling on HIV Infection and Other Conditions or Diseases of Public Health Importance<sup>o</sup>**

- (a) Programs provide counseling on HIV infection and other prevalent infectious diseases, such as hepatitis, sexually transmitted infections, and TB. Counseling also includes infectious disease prevention for at-risk patients, and the need for patients to adhere to treatment and to communicate honestly with the provider when treatment has begun.
- (b) Programs provide risk reduction education to patients.

## **(5) Medical Services**

Providing basic primary care onsite is highly recommended but not required. Programs make referrals for medical and psychiatric treatment when indicated. Staff members provide coordination of care also, and those staff responsible for making linkages should be knowledgeable about pharmacotherapy treatment (e.g., drug interactions, acute withdrawal, and overdose). Medications that have their effectiveness enhanced by directly observed therapy (DOT)—such as TB medications and psychiatric medications—can be effectively dispensed with the daily opioid dose. Likewise, psychotropic medications, which are indicated but subject to abuse, may be given through DOT.

42 CFR § 8.12(f) (6) *Drug abuse testing services*. OTPs must provide adequate testing or analysis for drugs of abuse, including at least eight random drug abuse tests per year, per patient, in maintenance treatment, in accordance with generally accepted clinical practice. For patients in short-term detoxification treatment, the OTP shall perform at least one initial drug abuse test. For patients receiving long-term detoxification treatment, the program shall perform initial and monthly random tests on each patient.

### **S. Testing for Drug Use**

- (1) Programs use drug and alcohol screening and testing as aids in monitoring and evaluating a patient's progress in treatment.
- (2) All treatment personnel in a medication-assisted treatment program understand the benefits and the limitations of toxicological testing procedures.
- (3) Programs collect all urine or other toxicological specimens in a therapeutic context that suggests trust and respect, and minimizes falsification. Reliance on direct observation, although necessary for some patients, is neither necessary nor appropriate for all patients.
- (4) Clinicians should determine the drug-testing regime by analyzing community drug-use patterns and individual medical indications. Testing may include opiates, benzodiazepines, barbiturates, cocaine, marijuana, methadone (and its metabolites), amphetamines, and alcohol, but testing is not limited to these substances.
- (5) It is strongly recommended that barbiturates and alcohol be included in drug screening and testing panels. Alcohol is the most widely used mood-altering substance in the United States, and barbiturates are often prescribed for detoxification and chronic seizure disorders. Detection of barbiturates or alcohol is important in ongoing assessment, treatment planning, and medication management.
- (6) Workplace Standards established by the Center for Substance Abuse Prevention are not appropriate for patients in the treatment context. The procedures and methodology for Workplace Standards employ a forensic approach that is entirely different from the therapeutic approach to treatment used in the clinical setting.
- (7) Program staff addresses results of toxicology testing with patients promptly. Programs document in the patient record both the results of toxicology tests and followup therapeutic interventions.
- (8) After the patient's initial admission drug testing, clinicians determine the frequency of toxicological testing by evaluating the clinical appropriateness for each patient in relation to the patient's stage in treatment.
- (9) The results of toxicological tests assist clinical staff in making treatment decisions regarding take-home medication privileges; however, clinicians do not base decisions about take-home medications or discharge solely on toxicology test reports.
- (10) Clinicians rapidly intervene to address the disclosure of illicit drug use, a positive drug test, or possible diversion of opioid medication, as evidenced by lack of opioids or related metabolites in drug toxicology tests.
- (11) Clinicians consider confirming the results of drug screening tests with additional testing. Treatment programs establish procedures for addressing potentially false positive and false negative urine or

other toxicology test results following principles outlined in TIP 43, “Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs” (CSAT 2005, chapter 9).

42 CFR § 8.12 (g) *Recordkeeping and patient confidentiality*. (1) OTPs shall establish and maintain a recordkeeping system that is adequate to document and monitor patient care. This system is required to comply with all Federal and State reporting requirements relevant to opioid drugs approved for use in treatment of opioid addiction. All records are required to be kept confidential in accordance with all applicable Federal and State requirements.

(2) OTPs shall include, as an essential part of the recordkeeping system, documentation in each patient’s record that the OTP made a good faith effort to review whether the patient is enrolled any other OTP. A patient enrolled in an OTP shall not be permitted to obtain treatment in any other OTP except in exceptional circumstances. If the medical director or program physician of the OTP in which the patient is enrolled determines that such exceptional circumstances exist, the patient may be granted permission to seek treatment at another OTP, provided the justification for finding exceptional circumstances is noted in the patient’s record both at the OTP in which the patient is enrolled and at the OTP that will provide the treatment.

### **T. Record Keeping and Documentation<sup>P</sup>**

All records required by 42 CFR § 8.12 (g) should be retained for a minimum of 3 years. **(1) Patient Records**

Patient records are confidential and updated in a timely manner. They contain legible entries, and are organized in a manner that facilitates access to specific elements of the record, as well as measurement of individual patient treatment outcomes. Programs should have record retention policies and safeguards for the destruction of old containers, labels, printouts, and program records. Program procedures should ensure security of electronic data transfers and protection of confidential data stored in computers. Clear guidelines should exist for access, transfer, and disposal of records, to include procedures under disaster conditions or in the event of program closure, in accordance with 42 CFR 2.

OTPs are required under 42 CFR §8.11(f) (3) to comply with the Federal confidentiality regulations set forth under 42 CFR Part 2. As such, records of the identity, diagnosis, prognosis, or treatment of any patient that are maintained in connection with the performance of any program or activity relating to substance abuse education, prevention, training, treatment, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the program shall, except as provided in subsection (e) of 42 CFR Part 2, be confidential and be disclosed only for the purposes or circumstances expressly authorized under subsection 42 CFR section 2(b).

Individual records maintained for each patient contain the following:

- (a) Identification and basic demographic data and results of the screening process. In lieu of patient identification data, each file may bear a unique identifying code that gives reliable access to such required identification information. All information should be accessible and understandable to appropriate authorities.
- (b) Documentation of compliance with the approved central registry system (if applicable) or an alternative mechanism to avoid dual registration.
- (c) The initial assessment report.

- (d) Narrative bio-psycho-social history, prepared within approximately 30 days of the patient's admission or as required by State regulation.
- (e) Medical reports, including results of physical examination; past and family medical history; review of systems; nursing notes; laboratory reports, including results of regular toxicology screens; and progress notes, including documentation of all medications and dosages. Information in the medical record is entered by physicians and other licensed health professionals.
- (f) Dated case entries of all significant contacts with patients, including a record of each counseling session, in chronological order.
- (g) Dates and results of case conferences for patients.
- (h) The treatment plan, and any amendments to it; quarterly reviews and updates of the assessment and treatment plan for the first year of continuous treatment; semiannual assessment and treatment plan updates for subsequent years; and in subsequent years, a semiannual summary by the counselor that includes an evaluation of the existing treatment plan and the patient's response to treatment.
- (i) Documentation that all services listed in the treatment plan are available, and actually have been provided.
- (j) A written report of the process and factors considered in decisions impacting patient treatment (e.g., take-home medication privileges, changes in counseling sessions, changes in frequency of drug tests) or any other significant change in treatment, both positive and negative.
- (k) A record of correspondence with patient, family members, and other individuals, and a record of each referral for service and its results.
- (l) Documentation that the patient received a copy of the program's rules and regulations and a statement of patients' rights and responsibilities, and that these items were discussed with her or him.
- (m) Consent forms; release(s) of information; prescription documentation; and travel, employment, "take-home" documentation, and so forth.
- (n) A closing summary, including reasons for discharge and any referral. In the case of death, the cause of death is documented.

## **(2) Records of Storage, Dispensing, and Administering Opioid Medication**

- (a) Each program has policies and procedures consistent with DEA statutes and regulations.
- (b) Each medication order and dosage change is written on an acceptable order sheet signed by the physician.
  - (i) Each dosage dispensed, prepared, or received is recorded and accounted for by signed notation, in a manner that creates a perpetual and accurate inventory of all medications, including controlled substances in stock at all times.

- (ii) Every dose is recorded on an administration sheet, at the time that the dose is administered or dispensed, and recorded on the patient's individual medication dose history.
  - (iii) The qualified person administering or dispensing medications signs his or her name or initials at each notation.
  - (iv) If initials are used, the full signature of the qualified person administering or dispensing appears at the end of each page of the medication sheet.
  - (v) The medication dose is totaled in milligrams daily.
- (c) Programs have a procedure for calibrating medication-dispensing instruments, consistent with manufacturers' recommendations, to ensure accurate patient dosing and substance tracking.

### **(3) Avoiding Multiple Program Enrollments**

- (a) Reasonable measures are taken to prevent patients from enrolling in treatment provided by more than one clinic or individual practitioner. These measures are commensurate with the severity of the problem and its documented consequences. In some cases, an OTP may, after obtaining patient consent, contact other OTPs within a reasonable geographic distance (100 miles) to verify that a patient is not enrolled in another OTP.

42 CFR § 8.12 (h) *Medication administration, dispensing, and use.* (1) OTPs must ensure that opioid agonist treatment medications are administered or dispensed only by a practitioner licensed under the appropriate State law and registered under the appropriate State and Federal laws to administer or dispense opioid drugs, or by an agent of such a practitioner, supervised by and under the order of the licensed practitioner. This agent is required to be a pharmacist, registered nurse, or licensed practical nurse, or any other healthcare professional authorized by Federal and State law to administer or dispense opioid drugs.

(2) OTPs shall use only those opioid agonist treatment medications that are approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for use in the treatment of opioid addiction. In addition, OTPs who are fully compliant with the protocol of an investigational use of a drug and other conditions set forth in the application may administer a drug that has been authorized by the Food and Drug Administration under an investigational new drug application under section 505(i) of the Federal Food, Drug, and Cosmetic Act for investigational use in the treatment of opioid addiction. Currently, the following opioid agonist treatment medications will be considered to be approved by the Food and Drug Administration for use in the treatment of opioid addiction:

- (i) Methadone; and
- (ii) Levomethadyl acetate (LAAM);
- (iii) Buprenorphine and buprenorphine combination products that have been approved for use in the treatment of opioid addiction.

(3) OTPs shall maintain current procedures that are adequate to ensure that the following dosage form and initial dosing requirements are met:

- (i) Methadone shall be administered or dispensed only in oral form and shall be formulated in such a way as to reduce its potential for parenteral abuse.
- (ii) For each new patient enrolled in a program, the initial dose of methadone shall not exceed 30 milligrams and the total dose for the first day shall not exceed 40 milligrams, unless the program physician documents in the patient's record that 40 milligrams did not suppress opiate abstinence symptoms.

(4) OTPs shall maintain current procedures adequate to ensure that each opioid agonist treatment medication used by the program is administered and dispensed in accordance with its approved product labeling. Dosing and administration decisions shall be made by a program physician familiar with the most up-to-date product labeling. These procedures must ensure that any significant deviations from the approved labeling, including deviations with regard to dose, frequency, or the conditions of use described in the approved labeling, are specifically documented in the patient's record.

**NOTE: Subutex and Suboxone Treatment for Patients Admitted to OTPs. SAMHSA-certified OTPs are authorized to dispense or administer (but not to prescribe) approved opioid treatment medications to patients admitted for opioid treatment. At this time, methadone and the buprenorphine products, Subutex and Suboxone, are approved for use in OTPs. Such treatment is not subject to the “30-patient limit” placed on physicians certified under the Drug Addiction Treatment Act (DATA) of 2000 or to the 100-patient limit placed on physicians under The Office of National Drug Control Policy Reauthorization Act of 2006. In addition, the special credentialing and 8-hour training requirements under that law do not apply to methadone and buprenorphine treatment for patients admitted to an OTP.**

**Subutex and Suboxone Treatment for Patients Treated by “Waivered Physicians.” Physicians may seek and obtain a “waiver” under the DATA of 2000. If qualified, the physician is authorized to prescribe or dispense Subutex or Suboxone for up to 100 patients at any given time. The DATA does not limit the treatment settings for physicians with a waiver. Accordingly, the physician may treat patients in an office-based setting, a residential or inpatient facility that is not an OTP, or in an OTP (including as an OTP physician), as long as the total number of patients treated at any one time does not exceed 100.**

#### **U. Guidelines for Therapeutic Dosage<sup>d</sup> (1)**

##### **General Dosage Principles**

- (a) The physician employs clinical judgment to determine the individual dose of opioid medication. The physician should have obtained program treatment privileges and should be knowledgeable about, and experienced in, addiction medicine including medication-assisted treatment.<sup>r</sup>
- (b) Maintenance medication doses are sufficient to produce the desired response in the patient for the desired duration of time, with allowance for a margin of effectiveness and safety.
- (c) When necessary to withdraw the patient from opioid treatment, the medically supervised withdrawal protocol will be of sufficient duration for patient safety.
- (d) Program-wide dose caps or ceilings are contrary to the principle of individualized treatment, and programs should not establish them. Programs avoid establishing procedures or policies that hinder making patient dosage adjustments whenever indicated.
- (e) Effective therapy involving medication-assisted treatment has the following desired outcomes:
  - (i) Preventing the onset of subjective and/or objective signs of opioid abstinence syndrome for at least 24 hours
  - (ii) Reducing or eliminating the drug craving routinely experienced by the patient

- (iii) Blocking the euphoric effects of any illicitly acquired, self-administered opioids, without inducing undesirable effects experienced by the patient or noticed by other observers.

## (2) Maintenance Therapy

- (a) A medical evaluation, including documented history and physical examination, support the judgment by the physician and/or appropriately licensed practitioner that the patient is a suitable candidate for opioid therapy.
- (b) The initial full-day dose of medication is based on the physician's evaluation of the history and present condition of the patient. The physician should also take into account local conditions, such as the relative purity of available drugs and the source of the drugs, whether the patient illicitly purchased or obtained them from friends or family members. Medication dosage is also based on the physician's assessment and evaluation of other medications that the patient reports taking, including OTC drugs, prescription medications, and prescription medications containing controlled substances.<sup>5</sup>
- (c) The first dose of any opioid treatment medication should be low if a patient's opioid tolerance is believed to be low, the history of opioid use is uncertain, or no signs of opioid withdrawal are evident. Regulations stipulate that the initial dose of methadone should not exceed 30 mg. The physician considers carefully the reasons for exceeding an initial dose of 30 mg and documents these reasons in the clinical record. The total amount of medication administered should not exceed 40 mg per day, unless the physician documents that 40 mg did not suppress opiate abstinence symptoms after a 3-hour period of observation. Patients abusing diverted, prescribed opioids alone may also require a low initial dose of methadone. The physician should calculate the dosage based on standard dose conversion tables and the patient's recent amount of opioid intake. During the induction phase, caution should be exercised regarding an overly rapid increase in dosage because of the long half-life of methadone. As a suggestion, once the patient reaches a dose of 60 mg per day, it may be medically indicated to maintain a stable dosage amount for 3 to 5 days before further increasing the dosage, depending on the patient's clinical status and symptoms.
- (d) Initial doses of buprenorphine or LAAM (if reintroduced for dispensing) and other approved medications should be based on the package insert. The physician documents the justification for any deviations from this principle.
- (e) The total dose of medication and the interval between doses may require adjustments for the patient who has concurrent health conditions or atypical metabolic patterns, or if the patient takes other prescribed medications that alter rates of opioid medication metabolism.
- (f) Programs do not adjust medication doses to reinforce positive behavior or to punish negative behavior. For example, a patient's noncompliance with a treatment plan, including a positive toxicology screen, should not necessarily result in a decreased dosage. In fact, in certain circumstances this may indicate the need for an increased dosage.
- (g) Programs continue medication-assisted treatment as long as the patient derives benefit from treatment and desires treatment. There should be no fixed length of time in treatment. In fact, indefinite medication-assisted treatment may be clinically indicated. The physician should also be prudent in considering other medications during the course of treatment, as clinically indicated.



- (h) If a program switches from one generic formulation to another and differences in effective dose cause clinically relevant complaints, the physician may decide to adjust the medication dosage. Additionally, physicians should exercise caution when a patient has missed several doses, because patient tolerance may have changed over time.
- (i) The program should have the capability to obtain medication blood levels when clinically indicated.

42 CFR § 8.12 (h) (4) (i) Unsupervised or “take-home” use. To limit the potential for diversion of opioid agonist treatment medications to the illicit market, opioid agonist treatment medications dispensed to patients for unsupervised use shall be subject to the following requirements.

(1) Any patient in comprehensive maintenance treatment may receive a single take-home dose for a day that the clinic is closed for business, including Sundays and State and Federal holidays.

(2) Treatment program decisions on dispensing opioid treatment medications to patients for unsupervised use beyond that set forth in paragraph (i) (1) of this section, shall be determined by the medical director. In determining which patients may be permitted unsupervised use, the medical director shall consider the following take-home criteria in determining whether a patient is responsible in handling opioid drugs for unsupervised use.

- (i) Absence of recent abuse of drugs (opioid or nonnarcotic), including alcohol;
- (ii) Regularity of clinic attendance;
- (iii) Absence of serious behavioral problems at the clinic;
- (iv) Absence of known recent criminal activity, e.g., drug dealing;
- (v) Stability of the patient’s home environment and social relationships;
- (vi) Length of time in comprehensive maintenance treatment;
- (vii) Assurance that take-home medication can be safely stored within the patient’s home; and
- (viii) Whether the rehabilitative benefit the patient derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion.

(3) Such determinations and the basis for such determinations, consistent with the criteria outlined in paragraph (i) (2) of this section, shall be documented in the patient’s medical record. If it is determined that a patient is responsible in handling opioid drugs, the following restrictions apply:

- (i) During the first 90 days of treatment, the take-home supply (beyond that of paragraph (i) (1) of this section) is limited to a single dose each week and the patient shall ingest all other doses under appropriate supervision as provided for under the regulations in this subpart.
- (ii) In the second 90 days of treatment, the take-home supply (beyond that of paragraph (i) (1) of this section) is two doses per week.
- (iii) In the third 90 days of treatment, the take-home supply (beyond that of paragraph (i) (1) of this section) is three doses per week.
- (iv) In the remaining months of the first year, a patient may be given a maximum 6-day supply of take-home medication.
- (v) After 1 year of continuous treatment, a patient may be given a maximum 2-week supply of take-home medication.

- (vi) After 2 years of continuous treatment, a patient may be given a maximum 1-month supply of take-home medication, but must make monthly visits.
- (4) No medications shall be dispensed to patients in short-term detoxification treatment or interim maintenance treatment for unsupervised or take-home use.
- (5) OTPs must maintain current procedures adequate to identify the theft or diversion of take-home medications, including labeling containers with the OTP's name, address, and telephone number. Programs also must ensure that take-home supplies are packaged in a manner that is designed to reduce the risk of accidental ingestion, including child-proof containers (see Poison Prevention Packaging Act, Public Law 91-601 (15 U.S.C. 1471 et seq.)).

## V. Unsupervised Approved Use (Take-Home Medication)<sup>†</sup>

### (1) Approving Take-Home Medication

- (a) In determining patient eligibility for *any* take-home medication, including a single take-home dose for a day that the clinic is closed for business, such as Sunday or a State or Federal holiday, the program physician considers the eight-point criteria and employs good clinical judgment.

Take-home medication is a valuable therapeutic tool and is part of an individualized treatment plan. Providing medication for unsupervised use is a reflection of the physician's judgment and staff's assessment of a patient's behavior while in treatment. Time in treatment is also an important factor. Program policies that do not permit take-homes for any patients are unacceptable, because these policies preclude individualized patient care. Take-home medication often becomes a critical issue for patients who are deciding whether to enter and remain in treatment. Program staff members use discretion in customizing medication schedules for each patient, according to that patient's best interests. Physicians and staff members should consider public health issues in approving take-home medication (e.g., preventing diversion, ensuring safe storage and security of medication, preventing overdoses). Staff should ensure that policies for approval of take-home medication do not create barriers to patients' continuing in treatment. Program policies foster decisions about entering and remaining in medication-assisted treatment based on medical factors.

A multidisciplinary team, typically led by the primary clinician, provides recommendations and essential input for review, while a physician makes the final decision about approving take-home medication. Physicians and staff members review decisions periodically, as clinically appropriate, and document them in the patient record. The review should consider the eight-point criteria and other relevant clinical factors. The physician should note conclusions reached in this review in the patient's record.

- (b) Programs should exercise caution when dispensing Subutex; Suboxone is the preferred medication for take-home dispensing (or prescriptions) unless otherwise clinically indicated. Treatment with Suboxone may follow guidelines described in CSAT's Treatment Improvement Protocol 40 (TIP 40) and other related CSAT publications. In following these guidelines, take-home medication decisions may differ if the patient is receiving Suboxone instead of methadone. Programs should use the CSAT patient exception process to justify take-home medications for Suboxone.<sup>†</sup>
- (c) Temporary take-home medication may be dispensed for documented family or medical emergencies or other exceptional circumstances.<sup>†</sup> In such emergencies, take-home medication

usually should not exceed 3 days. This does not obviate the need for a CSAT patient exception, only the need for preapproval.

**(2) Monitoring Unsupervised Use of Medications<sup>u</sup>**

- (a) Treatment programs monitor patients' dispensed take-home medications in a manner that complies with Federal regulations.
- (b) Program policies enable the physician to evaluate a patient's stability and response to take-home medication and to adjust dosages at regular intervals.

**(3) Medication Security<sup>v</sup>**

- (a) Program policies ensure responsible handling and secure storage of take-home medication in childproof containers.
- (b) Programs inform patients of their rights and responsibilities in ensuring the security of opioid medications.
- (c) Programs establish a mechanism for monitoring medications to prevent diversion.

**W. Patients' Rights**

**(1) Program Responsibilities**

- (a) Program administration obtains and is responsive to patients' feedback concerning their care.
- (b) Programs develop and implement policies and procedures to promote and protect patients' rights, as well as their health and well-being.
- (c) Programs inform patients, both verbally and in writing, of clinic rules and regulations and patients' rights and responsibilities.
- (d) Programs establish procedures to provide medication to traveling patients and consider providing take-home medication. At times, when patients must transfer to a different level of care or location, it may be appropriate for the program to provide sufficient medication for the patient until arrival at the new location. Under these circumstances, a record of chain of custody for transporting methadone to the new program may be required. Please see Standard and Example Forms, p. 64 for an example of the Chain-of-Custody form.
- (e) Programs establish reimbursement expectations with the patient, and work with the patient to receive, through agreed procedures, reimbursement for services rendered. Programs establish processes to resolve patient's financial difficulties that might occur over the course of treatment. Programs also establish policies in the event of nonpayment.

**(2) Patients' Rights and Responsibilities<sup>w</sup>**

**(a) Informed Consent and Information Disclosure**

- (i) Patients have the right to receive accurate, easily understood information. Some require assistance in making informed health care decisions about choosing their health plans, professionals, and facilities.

(ii) At the time of admission, each patient is informed of patients' rights and responsibilities and of the program's rules and regulations regarding patient conduct, in a language that the patient understands. Patients who are unable to read have the rules and regulations explained verbally, and such interventions are documented. The patient receives a written copy of these rights, including the following information:

- Programs provide treatment that is fair and impartial, regardless of race, sex, age, and source of payment, and that conveys a sense of dignity and trust to the patient.
- Programs provide treatment according to accepted clinical practice and community standards of care.

(iii) Patients' rights and responsibilities are posted at the treatment site and are reviewed with the patient following admission, at the end of the stabilization period, and when any changes have been made to the list of rights and responsibilities.

The patients are offered a written acknowledgment to sign, indicating that patients' rights and responsibilities and the program's rules and regulations have been explained. In the event the patient declines to sign this acknowledgment or expresses concerns, staff members should document the interaction.

(iv) Patients have the right to full disclosure of information about treatment and medication, including accommodations for those who do not speak English, or who are otherwise unable to read an informed consent form.

(v) Patients are informed about potential interactions with and adverse reactions to other substances, including those reactions that might result from interactions and adverse reactions to alcohol, other prescribed or OTC pharmacological agents, other medical procedures, and food.

(vi) Programs inform patients about the financial aspects of treatment, including the consequences of nonpayment of required fees.

(vii) Patients have the right to give informed consent prior to being involved in research projects, and the right to retain a copy of the informed consent form.

**(b) Choice of Treatment, Providers, and Plans**

(i) Patients have the right to choose health care providers that are sufficient, and that ensure access to appropriate high-quality health care.

(ii) Each patient receives an assessment, and then staff members notify the patient of acceptance into the program, as appropriate. In the case of denial of admission, the OTP provides a full explanation and a referral to another program based on the results of the initial assessment.

(iii) Patients receive services within the least restrictive and most accommodating environment possible. Procedures are in place to ensure that patients are provided a medication schedule (dosing times/program hours) that is the most accommodating and least intrusive and disruptive schedule for the majority of patients.

- (iv) Patients receive an individualized treatment plan, participate in the development of that plan, and receive treatment based on the plan. Periodically, the patient and staff will review the treatment plan jointly.
- (v) The program provides an adequate number of competent, qualified, and experienced professional clinical staff to implement and supervise the treatment plan, consistent with patient needs.
- (vi) Patients are informed about alternative medications, treatment alternatives, alternative modalities, and scientific advances affecting treatment.

**(c) Access to Emergency Services**

Patients have the right to access emergency health care services when and where the need arises. Health plans should provide payment when a patient presents to an emergency department with acute symptoms of sufficient severity—including severe pain—such that a “prudent layperson” could reasonably expect the absence of medical attention to result in placing that patient’s health in serious jeopardy, serious impairment to bodily functions, or serious dysfunction of any body organ or part.

**(d) Participation in Treatment Decisions**

Patients have the right and responsibility to participate fully in all decisions related to their health care. Patients who are unable to participate fully in treatment decisions have the right to representation by parents, guardians, family members, or other conservators.

**(e) Respect and Nondiscrimination**

Patients have the right to considerate, respectful, humane, and adequate care from all members of the health care system, at all times, and under all circumstances. An environment of mutual respect is essential to maintain a quality health care system.

Patients must not be discriminated against in the delivery of health care services, consistent with the benefits covered in their policy or as required by law, based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, sexual orientation, genetic information, or source of payment.

Programs have the responsibility to protect other patients, staff, and the public from a patient who acts out. However, programs also have a responsibility to determine the cause of that behavior so an appropriate referral can be made to an alternative method of care.

Treatment and other services may not be denied for patients who refuse to participate in research activities.

**(f) Confidentiality of Health Information and Patient Privacy<sup>x</sup>**

Patients have the right to communicate with health care providers in confidence and to have the confidentiality of their individually identifiable health care information protected. Patients also have the right to review and copy their own medical records and request amendments to their records.

Patients have a right to privacy, both inside and outside the program setting.

Patients have the right to confidentiality in accordance with Federal rules on confidentiality of medical records (42 CFR Part 2) and HIPAA (45 CFR Part 160 and Subparts A and E of part 164).

Patients have the right to be informed of the extent and limits of confidentiality, including the conditions under which information can be released without patient consent, the use of identifying information for purposes of a central registry, program evaluation, billing, and statutory requirements for reporting abuse.

**(g) Complaints and Appeals**

- (i) All patients have the right to a fair and efficient process for resolving differences with their health plans, health care providers, and the institutions that serve them, including a rigorous system of internal review and an independent system of external review.
- (ii) Patients are encouraged and assisted throughout treatment to understand and exercise their rights, including
  - Reporting, without fear of retribution, any instances of suspected abuse, neglect, or exploitation of patients being served in the program
  - A grievance and appeal process, in accordance with State laws and regulations
  - Input into program policies and services through patient satisfaction surveys
  - Telephone number of the State regulatory agency responsible for the program and name of a specific individual or title of the person within that agency who receives complaints
  - Please see Standard and Example forms, p. 63, for the Consent-to-Treatment form.

**(iii) Preventing, Investigating, and Resolving Patient Complaints**

Programs develop and display policies and patient grievance procedures that specify minimum elements of due process applicable to the program setting and resources, including the following:

- The right of patients to express verbally or in writing their dissatisfaction with or complaints about treatment received.
- The right to initiate grievance procedures.
- The right to be informed of the grievance procedures in a manner that can be understood, and a right to a copy of the procedures upon request. Such procedures should be clearly articulated, well publicized, posted in conspicuous places within the program, and easily available to patients. They include program rules, consequences of noncompliance, and procedures for filing a complaint and/or grievance.
- The right to receive a decision in writing, with the reasoning articulated.
- The right to appeal the decision to a final, unbiased source.

- The responsibility of the program to make every attempt, before a patient is discharged, to accommodate the patient's desire to remain in opioid therapy at an alternative treatment program.
- The use of involuntary withdrawal is only as a sanction of last resort that is accomplished in the most humane manner and consistent with the safety and well-being of staff, other patients, and the program.
- The program acts responsibly in that it does not change the patient's dose of opioids or other medications without the patient's knowledge, unless the patient signs a document waiving such consent.

**(h) Patient Responsibilities**

In a health care system that protects patients' rights, it is reasonable to expect and encourage patients to assume reasonable responsibilities. Greater individual involvement by patients in their care increases the likelihood of achieving the best outcomes and helps support quality improvement in a cost-conscious environment.

- (i) Patients should be involved in their treatment plans so that they become more likely to agree with them.
- (ii) Once the treatment plan is formulated, the patient should make every effort to follow it and discuss with the primary counselor any difficulties adhering to it. If possible, the patient may also recommend modifications in the treatment plan that make adherence to it easier.
- (iii) Patients should be encouraged to be honest with their primary counselor and discuss relapse concerns and possible barriers to following the treatment plan.
- (iv) If relapse occurs, the patient works with the counselor and is involved in contingency plans and in formulating a modified treatment plan.

## Endnotes

### a. Program Emergencies:

#### **Guidance for Treating OTP Patients From Areas Affected by Emergency Closure of Programs in the Event of a Disaster**

On August 31, 2005, SAMHSA issued guidance to the State Methadone Authorities (SMAs) and OTPs in those States directly affected by Hurricane Katrina. That guidance can be found at <http://dpt.samhsa.gov> and addresses patients in OTPs, as well as persons dependent on opioids who are not enrolled in addiction treatment.

**Guidance:** Programs receiving displaced patients should make every effort to contact the home treatment program of people who have had to evacuate the area in which they live after an emergency or disaster. Information about the program may be obtained from the OTP Directory on the DPT Web site (referenced above) or at the SAMHSA Substance Abuse Treatment Facility Locator at: <http://dasis3.samhsa.gov/>. In an emergency, program personnel may disclose information to the program medical director, program physician, registered nurse, or dosing nurse without a patient's signed consent. If unable to contact the patient's home program, the OTP receiving a displaced patient should follow procedures listed below, along with existing emergency plans:

- The emergency guest patient should show a valid picture identification that includes an address in close proximity to the area affected.
- The patient should show some type of proof that indicates the patient was receiving services from a clinic located in one of the affected areas, for example, a medication bottle, program identification card, or a receipt for payment of fees, etc. In cases in which the patient does not have any items of proof including picture identification, the physician should use his or her best medical judgment, combined with a stat drug test for the presence of methadone (lab test with quick turnaround, dipstick, or similar procedure).
- OTP staff may administer the amount of medication that the patient reports as his or her current dose; however, please remind each patient that the dose that is reported will be verified with the home program as soon as possible. It may be prudent to closely observe an unknown patient for several hours postadministration to ensure that the dosage decision was correct, or take appropriate medical action in the event the dose was too high. In cases in which the reported dose appears questionable, it is best to use good medical judgment when determining the dose level. In certain cases in which the patient can demonstrate no prior enrollment in treatment or medication dosage amount, it may be advisable to treat the patient as a new admission, and follow initial dosing procedures for a routine admission. (See 42 CFR § 8.12 (h) (3) (ii).)
- Emergency guest patients should be medicated daily with take-home doses provided only for days that the program is closed (Sundays and holidays). The clinic should have a plan to administer methadone appropriately and safely on days or at times when the program is closed. If the patient's current take-home status is verified, take-home doses may be provided in accordance with State and Federal regulations (42 CFR Part 8). In the case of a patient who is unable to receive daily treatment at the program location due to medical hardship, travel restrictions, or other hardship, take-home medication for unsupervised use may be considered using the SMA-168, "Request-for-Exception" process.
- Documentation of services provided to displaced patients should be a priority for OTPs. The OTP should assign a clinic identification number and maintain a temporary medical record for each guest patient. Reasonable efforts should be made to contact the patient's home program periodically to verify patient information prior to dispensing medication. The results should be recorded in the temporary chart. OTP staff should record the day, date, and amount of medication administered to each patient along with any



observations made by the staff. As time passes and affected OTPs reopen, some patients may elect to remain in treatment at the receiving facility and change from guest to permanent status. On conclusion of the emergency treatment, the receiving program may be asked to report the number of patients treated and the types of services provided to the SMA and/or SAMHSA.

**Opioid-Dependent Displaced Patients Not Currently in Treatment:** There are individuals dependent on opioids—including heroin or prescription drugs—who may arrive at the guest treatment program seeking help as a result of the disruption in the supply of street drugs. OTPs may admit, treat, and dose these patients under existing guidelines and regulations. Initiation on buprenorphine products may be appropriate for patients new to medication-assisted treatment.

**Displaced Patients Treated by Pain Clinics:** Patients who were being treated for pain with methadone by a physician may contact an OTP when they run out of medication and have no access to the former treatment setting. The first response should be to refer the patient to a local physician, particularly a pain management specialist. Additionally, the SAMHSA guidelines provide the following guidance:

- Patients, in general, are not admitted to OTPs to receive opioids only for pain, but there are exceptions to this principle.
- Patients with a chronic pain disorder *and* physical dependence are managed by multidisciplinary teams that include pain and addiction medicine specialists. The site of such treatment may be in a medical clinic or in an OTP, depending on each patient’s need and the best utilization of available resources. Similarly, addiction patients maintained on methadone or buprenorphine are not prohibited from receiving needed pain treatment including, when appropriate, adequate doses of opioid analgesics.
- “Tapering” (discontinuation of opioid medications used during an acute pain treatment episode). The Narcotic Addiction Treatment Act and the Drug Addiction Treatment Act (DATA) were established to allow for maintenance and detoxification treatment, using certain opioid controlled substances like methadone and buprenorphine. These requirements and limitations in no way affect the ability of a practitioner to utilize opioids for the treatment of pain when acting in the usual course of medical practice. Consequently, when it is necessary to discontinue a patient’s opioid therapy for the treatment of pain by tapering or weaning doses, there are no restrictions, under Federal opioid treatment regulations, with respect to the drugs that may be used. Because this is not considered “detoxification” as it is applied to addiction treatment, no separate DEA registration as an OTP or DATA waiver requirements apply.
- Patients who are diagnosed with physical dependence and a pain disorder are not prohibited from receiving methadone or buprenorphine therapy for either maintenance or withdrawal in an OTP, if such a setting provides expertise or is the only source of treatment.

**b. Continuous Quality Improvement:** Many States already require written consent for all types of medical care. This is essential in a climate of increasing patient litigation and questions from insurers. Requests from managed care groups for treatment records, which are needed to re-certify patients for payment, require strict attention to Federal confidentiality regulations. Ethical conduct by program staff also requires attention and use of specific expectations and standards. Carefully specified grievance procedures are imperative and must be followed in all involuntary termination procedures. The currency of staff credentials may become a legal issue if a staff member is not properly licensed at the time of an incident or other adverse action.

**c. Events That Require Immediate Response and Investigation:** The specific event or incidents requiring preventive action, documentation, investigation, and corrective action will vary by program and patient’s characteristics. Such significant incidents or adverse events might include accidental injury on the premises, medication errors, unexpected patient deaths, harm to family members or others from ingesting a patient’s medication, selling drugs on the premises, medication diversion, harassment or abuse of patients by staff, and violence.

- d. Community Relations:** Before a new program moves in and opens its doors, there is a strong need to educate all entities affected by the program, including the medical community, neighbors, and those who provide support services.
- e. Professional Staff Credentials and Development:** While there are no set ratios in Federal regulations, four States (Rhode Island, Wisconsin, Georgia, and Texas) have a required client-to-counselor ratio of 50:1. Alabama has a required ratio of 30:1. Arkansas has a required client-to-counselor ratio of 40:1. All of these States allow for an increase in the ratio under certain circumstances.
- f. “Standing Orders”:** In some disciplines of medicine, “standing orders” refer to a practice where dosing (and, in some cases, admission) decisions are based on an algorithm that includes objective findings, time in treatment, and other factors—without the input of an authorized health professional (see above). Sometimes, program physicians issue standing orders that merely state that dose levels be adjusted on a PRN (“as needed”) basis. These types of standing orders do not reflect individualized care and are unacceptable.

There is always the exception or emergency situation when a verbal order may be issued by the physician, but these situations are rare. It is recommended that if standing orders are issued, that they be individualized, reasonable, time limited, and reviewed and signed within a 72-hour period. In addition, the physician should pay special attention to risk and liability concerns in such situations.

- g. Screening, Assessment, and Evaluation:** The initial assessment’s focus is usually on the patient’s admission to treatment and determining dosage level. A comprehensive examination is performed within approximately 30 days, usually after the patient is stable and able to participate fully. Other evaluations that may prove necessary include formal psychiatric and vocational assessments and ancillary medical workups. The program is responsible for making a serious attempt to refer and encourage the patient to obtain appropriate evaluations. The program is responsible for following up on the results. A patient reentering treatment may need a repeat examination, depending on the timing of the original exam. All patients also undergo periodic health assessments, including regular screenings based on clinical guidelines as appropriate for age and gender.
- h. Pregnancy:** Pregnant women are still denied methadone treatment because program staff members are reluctant to initiate medication on an outpatient basis, believing that hospitalization is necessary for induction or withdrawal to ensure that the fetus is not subjected to unnecessary stress. Another barrier is the case-management burden on program staff because of the multiple legal ramifications that exist. Because it is crucial that pregnant women engage in treatment for their addiction, OTPs should give priority to admitting pregnant patients at any point during pregnancy and to providing them with all necessary care, including adequate dosing strategies as well as referrals for prenatal and followup postpartum services.
- i. Retention in Treatment:** Studies suggest that the duration of retention in treatment is directly related to success in outcome (Gerstein et al. 1994, French et al. 1993, French & Zarkin 1992, Institute of Medicine 1990, Hubbard et al. 1989, Simpson et al. 1986). For patients who drop out of treatment, the outcome is often negative, whereas patients who remain in treatment, despite continued excessive use of alcohol or illicit drugs, tend to benefit from the treatment experience.
- j. Tapering Medication Dosage or Medically Supervised Withdrawal:** These guidelines focus on patients who have been participating in medication maintenance treatment, because research has shown maintenance treatment to be more successful than a regime of medical withdrawal (“detoxification”) for the majority of patients (Institute of Medicine 1995). Patients who are medically withdrawn without an adequate period of stabilization tend to have a high probability of relapse. Thus, the guidelines place less emphasis on issues of medical withdrawal of opioid-addicted persons, even though this modality has a role in the treatment armamentarium. Medical withdrawal from opioids is appropriate for persons who are not eligible for maintenance treatment or who do not elect this type of treatment, such as those on short- and long-term detoxification as defined in Federal regulation. Involuntary “administrative withdrawal” requires

that OTPs define and follow due process. No schedule for dose reductions will fit all patients; some individuals tolerate more rapid withdrawal than others do. The underlying goal is to have voluntary medically supervised withdrawal reflect a humane partnership between the patient and the physician.

- k. Medically Supervised Withdrawal:** Medically supervised withdrawal usually does not have the same time constraints associated with administrative withdrawal. As a result, programs may schedule a longer and more flexible dose reduction. In the case of patient-initiated, medically supervised withdrawal, however, the patient may impose a timeframe that may or may not affect the prognosis.
- l. Patients With Co-Occurring :** Patients who are diagnosed with physical dependence and a pain disorder may receive medication-assisted treatment for either maintenance or withdrawal in a program setting if such setting provides expertise or is the only source of treatment. When methadone is used for pain treatment, it usually requires multiple daily doses. Similarly, addiction patients maintained on medication-assisted treatment are not prohibited from receiving needed pain treatment including, when appropriate, adequate doses of opioid analgesics.
- m. Family involvement contributes to positive outcomes in treatment while providing benefits to the family members.** However, engaging family members who have become “burned out” or disengaged from the patient may be difficult. It may be useful to expand the concept of family to include the patient’s social network, significant others, persons in recovery (such as a sponsor), resources from the community (including the outpatient provider), and others at the patient’s request. Some OTPs use short-term groups to educate the family on medication-assisted treatment, substance use disorders, their effects on the family, and other family issues. Family counseling allows more participants to address their concerns with the patient. When appropriate, referrals for family treatment should be made, and confirmation that followup has occurred should be obtained. If needed, identification of the ongoing need for collaboration should occur with informed patient consent.
- n. Orientation to Treatment:** Take into account that the patient may be in withdrawal or intoxicated in the first days of treatment. Ongoing informed consent is necessary.
- o. HIV Counseling:** There is some research available on describing effectiveness of HIV counseling. CDC provides training and training materials. As mentioned in TIP 43, “Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs” (CSAT 2005), these materials may enhance services at OTPs.
- p. Record Keeping:** Programs use standard intake forms or identical data elements when possible. Programs should be efficient and avoid duplication in record keeping. At the same time, the program gathers sufficient data for outcome, cross-site, or other evaluations or studies, or to support managed care data requirements.
- q. Dosage:** The thrust of these guidelines is to keep the dosage guidelines for maintenance therapy as simple as possible, with broad latitude for exercising clinical judgment and minimal mention of dosage amounts or schedules. CSAT decided not to elaborate on the advisable waiting time before administering additional incremental doses of methadone after the initial dose, or to specify the amounts of any additional doses, although they did offer specific guidelines for initial dosing. TIP 43, “Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs” (CSAT 2005) discusses subsequent dosing during the induction and stabilization periods in detail.
- r. Dosing and administration decisions shall be made by the program physician and documented completely in the patient record.** Nurse practitioners and physician’s assistants who possess a valid DEA registration permitting them to prescribe scheduled drugs are recognized to provide medical services in OTPs in States that, in turn, accept and recognize their credentials to prescribe scheduled medications. Following the admission of patients by the program physician, the nurse practitioner or physician’s assistant in the OTP is empowered to provide medication services such as methadone and buprenorphine adjustments (increases/decreases), detoxification regimens, and medically supervised withdrawal.

**s. Patients' Outside Prescriptions:** OTPs should establish policies that relate to the various medications that patients may receive while in treatment. These include OTC medications and medications—some of which may contain controlled substances that physicians outside the treatment program prescribe for acute and chronic illnesses. The policies should follow two basic principles: (1) The patient should show all medications, including OTC medications and prescribed medications, to the program's medical staff. The patient should explain the purpose of the medication as the patient understands it. (2) If the patient presents a medication containing a controlled substance or other medication that may be considered dangerous in combination with opioids, the program physician should meet with the patient and discuss the reason for the prescription. It is strongly recommended that the program physician only conduct this meeting in order to facilitate patient trust and to obtain the patient's consent to contact the outside prescribing physician. Because the use of multiple controlled substances may have the potential for producing respiratory depression or other life-threatening effects, the physician should request that the patient agree to permit the physician to review all outside prescriptions, especially for the benzodiazepine class of drugs. The physician may decide to contact the outside prescribing physician and make a recommendation to the patient about whether a prescribed drug is appropriate while the patient is in opioid treatment. The coordination of the patient's care is paramount, and the physicians should consult with one another to determine the appropriate medications. The program physician also should discuss with the patient dependency and withdrawal issues resulting from continued use or abrupt discontinuance of controlled substances and modify the treatment plan if necessary.

**t. Exception Request and Record of Justification**

**Form SMA-168**

**42 CFR § 8.11 (h)**

In cases in which the patient's treatment needs require an exception to the regulations found in 42 CFR Part 8, the OTP physician may complete an **Exception Request and Record of Justification, SAMHSA Form SMA-168**. Frequently, these exceptions may be granted even if the patient has not followed all clinic rules, because without such an exception, the patient would have to choose between employment and treatment.

For a patient who does not satisfy the Federal time-in-treatment criterion to receive take-home medication, the OTP physician must complete, sign, and submit an SMA-168 Exception Request and Record of Justification. Without Federal approval of an Exception Request, the OTP may not dispense the take-home supply of medication to the patient for unsupervised use. The most important aspect of the exception request is to explain in detail the purpose and justification and to give a clear explanation of hardship—i.e., distance in miles, hours of employment, conflict with employment, and/or medical issue—so that the DPT reviewer is able to understand clearly the patient's situation and can make a decision.

The mechanisms for submitting SMA-168 follow:

1. The preferred method of submission is through the Internet. The program director may apply for the account by calling 1-866-687-2728. Once an account has been set up, the staff and physicians receive access to the Web site and a specific, individual signature password for signing and submitting the electronic form SMA-168. The processing time for a response is the same day, usually within hours.
2. In case of emergency, program staff may submit an SMA-168 through facsimile (fax) to 1-240-276-1630. The form may be downloaded from the DPT Web site at [www.dpt.samhsa.gov](http://www.dpt.samhsa.gov), or e-mailed or faxed if a verbal request is made, by calling 1-240-276-2700. The processing time for a response for a fax transmission may exceed 24 hours.

**Guest Dosing**

Guest dosing involves providing medication to a "guest patient" in a program in which the patient is not enrolled, such as when a patient travels to another city for a period of temporary employment and needs to receive medication. Guest dosing is recommended for patients who do not meet the criteria outlined in

42 CFR § 8.12 (i) (2) (i–viii). Guest dosing may prove helpful when a patient will be remaining in an area for a protracted period, and it is impractical to return to the patient’s home program routinely to pick up a supply of take-home medication. The patient, home program, and guest program should arrive at an agreement to provide the patient with clinical services, such as counseling, if the period for guest dosing exceeds 30 days.

- u. Discussion of Monitoring Patients’ Unsupervised Use of Medications:** To monitor patients receiving medication for unsupervised use, physicians need a thorough understanding of physiological issues, differences among laboratories, and factors that affect absorption, metabolism, and elimination of opiates. This knowledge is necessary to interpret a negative methadone and/or a toxicology test for methadone metabolites, for example.
- v. Opioid Treatment Patients and Temporary Residential Treatment:** Periodically, opioid treatment patients may require temporary residential treatment, long-term care, incarceration, etc. Other portions of this guideline address chain of custody for take-home supplies, and other issues that permit patients to continue maintenance during these periods. Occasionally, due to unforeseen circumstances, there are unused medication supply issues that need to be resolved.

Because an individual patient may not return unused controlled substance prescription medication to the OTP, the program should have a procedure to ensure medications are disposed of in a manner that does not allow the controlled substances to be easily diverted for illegal use.

#### **Guidelines for Security of Take-Home Medication**

Patients receiving unsupervised (take-home) medication should use locking containers to store their medication at home. The locking container provides a reasonably safe place for the medication at home but provides little in the way of security from the program to the patient’s home. Patients inconspicuously and safely transport take-home medication from the program to the home without the program mandating a specific type of locking container. In fact, the locked container challenges two regulatory issues: (1) if the locked container is publicly visible, it may offer a means to identify someone in treatment and violate patient confidentiality; and (2) the container’s visibility may identify the patient possessing take-home medication, and place the patient at risk for robbery or assault.

For patients reporting to the clinic once or twice per month, receiving 15- to 30-day supplies of medication, the OTP should dispense dry medication diskettes in one single bottle for ease of discrete transport home. Programs should also consider medication diskettes for patients using air transportation. Dispensing dry medications will mitigate any potential for bacterial growth in liquid media.

#### **Medication Security—Providing Medication to Patients Who Are Incarcerated, in Residential Treatment, Medically Compromised, or Homebound**

During the course of medication-assisted treatment, there may be occasions when a patient is unable to report to the program for routine observed ingestion of medication. This absence may occur because of illness, pregnancy, incarceration, participation in residential treatment, lack of transportation, and the like. When these situations occur, continuing the patient’s treatment safely while ensuring appropriate handling and delivery to the patient is a challenge for clinical staff.

This is usually accomplished by using a “Chain-of-Custody Record,” which is a document containing the signatures of all people who have handled the medication (see page 64). This record should also contain space for the patient to initial each day that the medication is administered, as well as space for the initials of the person who administered the medication. The patient and the person administering the medication should contact the program immediately if the medication seems altered in any way.

When the patient is unable to report to the program as required, a Chain-of-Custody Record is used to encourage a responsible person to take charge of the medication and place it under lock and key at the

offsite location. The same holds true for incarceration facilities and nursing homes that do not have methadone in stock.

For patients who are homebound, a family member who does not have a history of alcohol or drug abuse and whom the OTP staff members have met and screened may receive permission to pick up the medication. The OTP should request this through the SMA-168 and forward the exception request to the relevant State and Federal Government authorities.

When the Chain-of-Custody Record has been completed, it is to be returned to the program. The original of the record should be placed in the patient's medical record, and a copy may be placed in the Quality Assurance file, as needed.

w.(1) **Consumer Bill of Rights:** Adapted and expanded, in part, from the “Consumer Bill of Rights” drawn up by the Advisory Commission on Consumer Protection and Quality in the Health Care Industry— appointed by President Clinton on March 26, 1997, to “advise the President on changes occurring in the health care system and recommend measures as may be necessary to promote and assure health care quality and value, and protect consumers and workers in the health care system.”

(2) **Patients' Rights and Responsibilities:** Patients may undergo significant stress during admission, and programs should offer additional opportunities for them to review their rights and responsibilities once they are better able to understand them. Patients need this information in multiple formats, appropriate to culture, language, and literacy level. Examples include signs in the waiting room, pamphlets, electronic media (video, tapes), and “talk through” with staff.

x. **Privacy:** Internal controls on privacy are often overlooked in facility design and in staff-to-patient and patient-to-patient communications. Examples include windowed/open workspace; a cashier located in public area; untrained security guards; common medication dispensing areas; and hallway conversations about HIV/AIDS, failed urinalysis, or psychiatric medications. OTPs should take measures to correct such problems, when possible.



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**Appendix A. References**

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## **Appendix B. Guideline Panel**

On October 31 and November 1, 2005, CSAT convened a panel of experts in Washington, DC, to review and begin to revise the current “Guidelines for the Accreditation of Opioid Treatment Programs.” The Expert Panel members were asked to consider, in reviewing the current guidelines, issues such as the length of the processes, the consensus development process, the quality of the advice (as opposed to quantity), and whether or not supporting data exist.

The panel participants separated into four groups to review and suggest revisions to the guidelines. Participants considered the perspectives of regulation, science, and the burden of conformance to the guidelines. They also considered issues such as treatment settings, timelines for delivering care, and the extent to which the guidelines should be prescriptive. The four groups focused on the following overall themes:

1. Organizational Structure and Administrative Responsibilities
2. Individualized Patient Care
3. Medication Management
4. Medical Issues and Co-Occurring Disorders

The representatives of accreditation organizations sat in as observers within the breakout groups to provide information and clarification. They did not take part in the final group decisionmaking process, which resulted in the editing and updating of the current guidelines.

### **Accreditation Guidelines Expert Panel October 31–November 1, 2005**

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#### **Panelists**

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## Appendix C. Frequently Asked Questions

### I. SMA-162 Application Process

#### 1. Q—How does an OTP inform SAMHSA of program changes?

A—Submit an SMA-162 form. In Item 14 of the form, check the box that indicates why you are submitting the application. Choices that appear on the form are Provisional Certification, New Sponsor, New Medical Director, Relocation, Medication Unit, and Renewal.

You may access this form on the Internet at [www.dpt.samhsa.gov](http://www.dpt.samhsa.gov).

#### 2. Q—What do you check on the form for a generic program update? For example, if a new program director comes on board in my program, how do I inform SAMHSA of the change? How do I notify SAMHSA of other relevant changes to my organization?

A—You do not need to check a box on the form to submit a generic program update. However, SAMHSA prefers that you fill out an SMA-162 and attach an explanation of the change. You may also inform SAMHSA of the organizational change with a letter. Please fax the form (or letter) to 1–240–276–1630. You may also mail the form to the address listed below.

Substance Abuse and Mental Health Services Administration  
Office of Pharmacologic and Alternative Therapies  
Attention: OTP Certification Program  
Room 2-1086  
1 Choke Cherry Road  
Rockville, MD 20857

#### 3. Q—What do you do if you start a new program and do not have an FDA number?

A—Now that SAMHSA provides oversight for opioid addiction treatment under 42 CFR Part 8, the “FDA number” is now called a “SAMHSA number.” To request a SAMHSA number, please submit a completed SMA-162, and in Item 14 on the form, check the “Provisional Certification” box. SAMHSA will review your application for completeness using the checklist, included in your application packet, and will notify you of the need for additional information. After your State and the DEA have completed their OTP approval process and have notified SAMHSA, SAMHSA will complete the approval review. Once your program is approved, SAMHSA will assign a number to you.

#### 4. Q—What do you do if you are an existing program and do not know your SAMHSA number?

A—To find out your SAMHSA number, please [e-mail otp@samhsa.hhs.gov](mailto:otp@samhsa.hhs.gov) or call 1–240–276–2700.

#### 5. Q—Does an existing medication unit have to submit an SMA-162 separately from the original OTP?

A—No, we require only a single submission. Medication units are defined under Federal regulations as facilities, including community pharmacies that dispense treatment medications. The SAMHSA-certified OTP assumes all responsibilities for medication units. If the OTP already has an existing medication unit and the OTP is filing an SMA-162 with a program update, then the program needs to submit only one SMA-162 and the appropriate attachments. One of the attachments always will be a description of the medication unit along with the DEA registration number assigned to that medication unit. The medication unit’s DEA number will be different from the DEA number for the original OTP. For instructions on how to open a new medication unit, see the next question.

**6. Q—How does an OTP apply to open a new medication unit?**

**A**—Please submit an SMA-162 with all requested attachments and signed documents to SAMHSA. In Item 14 of the application, “Purpose of Application,” check off “Medication Unit.” After SAMHSA processes the form, it will forward its approval to the DEA, which will arrange an inspection. The program should also submit any required materials to the State Methadone Authority (SMA) to seek State approval, as appropriate. Once the DEA approves the medication unit, it will assign a new registration number for that medication unit. The SAMHSA-assigned number usually will stay the same for both the original site and the medication unit.

**7. Q—Does “Program Sponsor” on the SMA-162 refer to a program or a person?**

**A**—A Program Sponsor (Item 6) should always be a person’s name, not the name of a program. The sponsor is the person who is legally responsible for the OTP and who serves as the formal contact between SAMHSA and the OTP.

**8. Q—How much notice does an OTP have to give when informing SAMHSA of a program change?**

**A**—OTPs should notify SAMHSA within 3 weeks of any change indicated in Items 6 and 10 (14?) of the SMA-162 (e.g., medical director or program sponsor).

**9. Q—What are the differences between provisional certification, certification, and accreditation?**

- **Certification** is the process by which SAMHSA determines that an OTP is qualified to provide opioid treatment under the Federal Opioid Treatment Standards. To become certified by SAMHSA, OTPs must successfully complete the accreditation process and meet other requirements enumerated in regulation 42 CFR Part 8. Once certified, programs must renew certification at least every 3 years.
- **Provisional Certification** is a temporary certification granted for up to 1 year for a new OTP until it becomes accredited. SAMHSA may grant provisional certification to an OTP that has applied for accreditation. Provisional certification is granted to OTPs that have submitted form SMA-162, along with a statement identifying the accreditation body to which the OTP has applied, the date on which the OTP applied for accreditation, the dates of any accreditation surveys that have taken place or are expected to take place, and the expected schedule for completing the accreditation process. Provisional certification may be granted for 1 year, unless SAMHSA determines that the patient’s health would be adversely affected by the granting of provisional certification.
- **Accreditation** is defined by 42 CFR § 8.2 as the process of review and acceptance by an accreditation body. An accreditation body is an independent, not-for-profit organization or State governmental entity that has been approved by SAMHSA under § 8.3 to accredit OTPs that use opioid agonist treatment medications. An OTP must receive accreditation before it may be certified by SAMHSA.

**10. Q—When a new OTP is just getting started, how much time does it have to get accreditation?**

**A**—Up to 1 year. New OTPs must apply for accreditation with a SAMHSA-approved accreditation body and then apply to SAMHSA requesting provisional certification. With the application (SMA-162), the OTP should include a statement identifying the accreditation body to which the OTP has applied, the date on which the OTP applied for accreditation, the dates of any accreditation surveys that have taken place or are expected to take place, and the expected schedule for completing the accreditation process. A provisional certification will be granted for up to 1 year, unless SAMHSA determines that patient health would be adversely affected by the granting of provisional certification. The program must achieve accreditation within that same year.

## II. Detoxification Programs

### 1. Q—Is a detoxification program considered to be an OTP?

A—Yes. CFR defines an OTP as a “program or practitioner engaged in opioid treatment of individuals with an opioid agonist treatment medication.” The regulations—42 CFR § 8.11 (a) (1)—state that an OTP must have a current, valid certification from SAMHSA to be considered qualified by the Secretary of DHHS to dispense methadone, LAAM, or buprenorphine for the treatment of addiction. A unit of a hospital that intends to offer new detoxification services using methadone should apply to SAMHSA for provisional certification.

### 2. Q—Will SAMHSA require inpatient detoxification programs that use methadone to be accredited and certified? As a freestanding detoxification/rehabilitation facility dispensing methadone for detoxification only, will we be held to these accreditation/certification standards?

A—Yes. Title 42 of the CFR Part 8 addresses all forms of opioid treatment, including maintenance and detoxification treatment.

### 3. Q—If so, will the process differ in any way from what is being required of maintenance programs?

A—No. Detoxification programs are subject to the same standards as maintenance programs. Standards are detailed in the Final Rule (42 CFR § 8). OTPs providing inpatient detoxification services must be accredited and certified. Accreditation bodies may develop specific detoxification treatment accreditation standards and processes for surveying OTPs providing such services.

### 4. Q—Please comment on the guidelines for physicians and clinics who administer detoxification without SAMHSA accreditation.

A—Under the Narcotic Addiction Treatment Act of 1974, all practitioners who use narcotic drugs for treating opiate addiction must obtain a separate registration. However, according to the DEA, an exception to the registration requirement, known as the “3-day emergency exception”—21 CFR 1306.07(b)—allows a practitioner who is not separately registered as a narcotic treatment program to administer (but not prescribe) narcotic drugs to a patient for the purpose of relieving acute withdrawal symptoms while arranging for the patient’s referral for treatment, under the following conditions: (1) not more than 1 day’s medication may be administered or given to a patient at one time; (2) this treatment may not be carried out for more than 72 hours; (3) this 72-hour period cannot be renewed or extended.

The intent of 21 CFR 1306.07 (b) is to provide practitioner flexibility in emergencies in which a patient undergoing withdrawal needs treatment. In such emergencies, it is impractical to require practitioners to obtain a separate registration. The 72-hour exception offers an opioid-dependent individual relief from experiencing acute withdrawal symptoms while the physician arranges placement in a maintenance/detoxification treatment program. This provision was established to augment, not to circumvent, the separate registration requirement. This information is available at <http://www.deadiversion.usdoj.gov/drugreg/faq.htm>.

In addition, there are other situations in which registration and certification may not be required. The Final Rule, 42 CFR § 8.11 (1) (2), contains the following language:

Certification as an OTP will not be required for the maintenance or detoxification treatment of a patient who is admitted to a hospital or long-term care facility for the treatment of medical conditions other than opiate addiction and who requires maintenance or detoxification treatment during the period of his or her stay in that hospital or long-term care facility.

**5. Q—Are there restrictions on how many times a patient can be detoxified this way?**

A—The 3-day emergency exception cannot be renewed or extended. Because this is a DEA rule, please consult with DEA for further details.

**6. Q—The regulations state that, in order to have take-home medications, a person has to be in a comprehensive maintenance program, but long-term detoxification is not addressed. Old regulations did not allow take-homes for those on long-term detoxification. Is it the same with the new regulations?**

A—No. Both maintenance patients and long-term detoxification patients are eligible for take-home medications, while short-term detoxification patients are not.

**III. Take-Home Privileges****1. Q—The regulations regarding take-home privileges indicate that a patient may have an extra take-home dose for the day that the clinic is closed. Can you make weekly take-homes adjacent to one-another, so that patients may receive take-homes for a longer period around the weekend?**

A—Sometimes. You may not give this privilege to all patients in a clinic. This practice may be justified for an individual patient on occasion. By granting take-home privileges, you are acknowledging that the patient meets the eight criteria in the regulations for take-home medications. The take-home schedule must be tailored to each patient. It also would not be appropriate to give a relatively new patient take-home medications in such a manner because it may place the patient at risk for relapse or tempt the patient to divert medication for illegal use.

**2. Q—Our program is considering dispensing tablets for patients who have take-home privileges. Is this a diversion risk?**

A—All opioid treatment medications pose a risk of diversion. The physician must determine that a patient is responsible enough to receive solid take-home medication. Diskettes formulated to reduce the potential for intravenous administration pose less diversion risk than tablets.

**3. Q—The regulations state that a person on short-term detoxification cannot have take-home medications. How does this apply to the programs that want to close on a holiday or on a Sunday?**

A—The previous regulation prohibited take-home medication for both short- and long-term detoxification patients. Under the previous regulation, FDA approved program-wide exemptions to permit holiday take-home medications. SAMHSA will review annual program-wide exemption requests to permit take-home dosages for holidays for patients in short-term detoxification treatment.

**4. Q—The regulations state that in order to have take-home medications, a person has to be in a comprehensive maintenance program. Old regulations did not allow take-homes for those on long-term detoxification. Is it the same with the new regulations?**

A—No. Both maintenance patients and long-term detoxification patients are eligible for take-home medications, while short-term detoxification patients are not.

**5. Q—Assume that a patient is in a comprehensive maintenance program, is on take-home status, and requests a medically supervised withdrawal. Can she or he remain on take-homes during the withdrawal period?**

A—Yes. The patient was admitted to maintenance treatment. Take-homes would be permitted.



## IV. Treatment

**1. Q—The regulation regarding Medical Examination Services (§ 8.12 (f) (2), Initial Medical Examination Services) states that the initial exam should take place before admission or within the first 14 days. Can the patient begin treatment immediately on admission and see the physician any time within that 14-day period, or must she or he see the physician before treatment commences?**

**A—**The statement preceding the question does not reflect the meaning of the language in the regulation. 42 CFR § 8.12 (f) (2) addresses this question as follows: OTPs shall require each patient to undergo a complete, fully documented physical examination by a program physician or a primary care physician or an authorized health care professional under the supervision of a program physician, before admission to the OTP. The full medical examination, including the results of serology and other tests, must be completed within 14 days following admission.

**2. Q—When a person in treatment for opiate addiction tests negative for opiates, but tests positive for another drug, can we keep him or her in treatment?**

**A—**Yes. SAMHSA encourages OTPs to ensure that the abuse of drugs other than opiates is addressed in treatment. The OTP should provide appropriate counseling and other treatment if it identifies abuse of other drugs or alcohol as a problem. When necessary, the OTP may refer the patient to another program for additional treatment services. For further information, please refer to the Treatment Improvement Protocols at <http://www.treatment.org/Externals/tips.html> online.

**3. Q—The SAMHSA regulations do not state the drugs for which patients should be tested. How do we determine the drugs for which to test?**

**A—**The regulations require that OTPs perform adequate testing services at minimum intervals. SAMHSA guidelines recommend that drug-screening tests should include tests for opiates, methadone, amphetamines, cocaine, and barbiturates. Testing for other drug use should be determined by community drug use patterns or individual medical indications. Accreditation bodies may adopt a more flexible standard, which would allow the OTP not to test for drugs that are not commonly used in that particular community or population. The accreditation bodies may offer additional guidance on this subject.

**4. Q—What happens when drug testing reveals use of specific drugs, such as amphetamines and barbiturates?**

**A—**The OTP should provide appropriate counseling and other treatment if abuse of other drugs is identified as a problem. When necessary, the OTP may refer patients to other programs for additional treatment services.

**5. Q—Until May 2001 (when the regulations changed), the FDA required that all clinics use an FDA Consent to Methadone Treatment form. On that form, it stated that breastfeeding was not recommended for female patients. As clinics, we were required by law to have patients sign this form. How should we advise pregnant or lactating patients?**

**A—**Regulations require that OTPs obtain every patient’s informed consent to treatment; however, there is no longer a standard, required form. OTPs should develop their own form for consent to treatment. The Accreditation Guidelines state, “The program encourages breastfeeding during methadone/LAAM therapy unless medically contraindicated, e.g., by the presence of HIV/AIDS infection in the mother.” However, this decision is a medical decision that the physician and the mother should make.

**6. Q—Is an FDA consent form still required?**

A—No. Informed consent is still required, but SAMHSA does not plan to create a standardized consent form. OTPs must develop their own.

**7. Q—Although the new regulations require clinics to obtain informed consent to treatment, it seems that many clinics are still using the old FDA form and just giving it a new name. Is this acceptable?**

A—No. SAMHSA recommends that OTPs no longer use the old “Consent to Methadone Treatment” form. It would be better to develop a new informed consent to treatment to comport with the new regulations, scientific advances in treatment, and OTP needs.

**8. Q—Scenario: Within a few days of a discharge, a client feels as though she wants to use again. She calls the OTP from which she was discharged to request continued treatment. What needs to be in place before she can be readmitted? Does she have to have used again?**

A—No. The patient may be readmitted after the physician examines the patient and writes an admission order. The patient does not have to use drugs again to be admitted.

**V. Medication****1. Q—Is there a health problem associated with LAAM?**

A—There has been some evidence of a rare condition involving cardiotoxicity associated with LAAM.

**2. Q—Some pain management clinics are dispensing methadone. How can an OTP tell whether a person is legally medicated or using illicit drugs?**

A—We are unaware of a foolproof way to determine this. However, a patient may sign consent for release of information and allow a pain management clinic to verify to an OTP that she or he is receiving opioid treatment.

**3. Q—What can we do about the dose cap restriction?**

A—The new regulation does not refer to dosage caps. The “Guidelines for the Accreditation of OTPs” discourage dosage caps. OTP and physician education appears to be the best approach for encouraging individualized treatment, with no dosage caps.

**4. Q—What is your interpretation of this statement: “Methadone should be dispensed only in oral form and shall be formulated in such a way as to reduce its potential for parenteral abuse” (42 CFR § 8.12 (h) (3) (i))?**

A—Methadone should be dispensed orally only. Parenteral and nonoral forms are prohibited in opioid addiction treatment. Previous regulations restricted methadone dispensing for addiction treatment to liquid only; however, the new regulations removed the liquid-only restriction. Diskettes and tablets are formulated to comport with standards; approved solid medications are now acceptable forms of administration of opioid medication. Diskettes formulated to reduce the potential for intravenous administration pose less risk of a diversion than tablets.

**5. Q—What is the new regulation regarding the initial opioid medication dose?**

**A—**The very first dose administered may not exceed 30 mg. However, the total dose for the first day may go up to 40 mg, but shall not exceed 40 mg unless the program physician determines and documents in the patient’s record that 40 mg did not suppress opiate abstinence symptoms (CFR § 8.12 (h) (3) (ii)).

**VI. State-Specific Questions**

**1. Q—A few States and OTPs have recognized that the new medication take-home schedule outlined under 42 CFR § 8.12 (i) is different from the schedule outlined in the previous regulations. These parties contend that the previous regulations permit one or two additional take-home medication doses after the first 90 days of treatment when compared to the new regulation. The States and OTPs question whether statewide exemptions can be approved to permit application of the previous regulatory schedule between 90 and 270 days. Please clarify.**

**A—**The take-home schedule in the final rule was modified from the schedule in the proposal for clarity and reflects a considerable number of comments. In addition, the new language incorporates the new provision, which allows LAAM take-home medications. Finally, the new take-home schedule resembles the schedule in the “Accreditation Guidelines,” which were part of the accreditation evaluation project.

The new schedule, which includes more intervals in the initial year of treatment, reflects a balance, with patients in treatment beyond 1 year deemed eligible for a 2-week supply. While the previous regulation may have permitted an additional take-home dose of methadone after the 1st quarter of treatment, those regulations permitted only a maximum of six take-home doses after 3 years of treatment. The new regulations, on the other hand, permit eligible patients to have a 6-day supply of take-home medication after 270 days of treatment, 2 weeks of take-homes after 1 year, and a 1-month supply after 2 years of treatment.

While SAMHSA has reviewed and will continue to accept single-patient exception requests, SAMHSA has not approved statewide or program-wide exemptions to permit OTPs to dispense take-homes in accordance with the previous regulatory schedule.

**2. Q—In Minnesota, we have always required a lock box for take-homes from methadone clinics, primarily to prevent accidental ingestion by children and the like. This has not been a Minnesota Rule/Statute; rather, we have used FDA ruling and interpretation for this purpose. Page 4098 of the Federal regulation of January 17, 2001, under take-home criteria (vii), states, “Assurance that take-home medication can be safely stored within the patient’s home . . . .”**

**Is it safe to interpret this as continuing to require a lock box for take-homes?**

**A—**No. The regulations (42 CFR 8.12 (i) (5)) require the use of childproof containers and do not specify that a lock box is a requirement. We were unable to locate an explicit requirement in FDA rules addressing the use of lock boxes for take-home supplies. In the past, there has been an implicit understanding that lock boxes should be used, based on the need to prevent accidental ingestion by children. However, the “Accreditation Guidelines” state “program policies ensure responsible handling and storage of ‘take home’ medication in childproof containers.”

**3. Q—Will the new regulations override a State’s authority to prohibit opioid agonist treatment (methadone/LAAM) programs?**

**A—**No. The oversight of methadone and LAAM will still be a tripartite system involving the State, HHS, and DEA. States regulate the practice of medicine and, therefore, may regulate methadone and LAAM treatment. There are other State and local regulatory activities, such as certificates of need, zoning, and licensure; these

may affect the number, size, and locations of methadone programs. State and local regulations are not affected by the change in DHHS regulations.

On the other hand, since the new Federal regulations were proposed, it is encouraging to note that four States, which formerly did not have methadone treatment, now have methadone treatment available. These States are West Virginia, Vermont, New Hampshire, and Mississippi.

## **VII. Drug Testing**

### **1. Q—Our OTP is exploring the use of oral solution testing. Can an OTP use alternatives to urine specimen testing to fulfill the drug testing requirements under the Federal opioid treatment regulations?**

**A—**Neither the previous FDA regulations nor the new SAMHSA rules specify urine as the only type of biological sample that can be tested; however, they do say: “OTPs must provide adequate testing or analysis for drugs of abuse, including at least eight random drug abuse tests per year, per patient in maintenance treatment, in accordance with generally accepted clinical practices.”

Drug testing is considered a medical service and is an important component in treatment. Test results are used to determine whether dosing adjustments or other treatment interventions are needed. In addition, drug test results are important in determining whether a patient is stable enough to receive medications for unsupervised use. Accordingly, the OTP medical director assumes responsibility for the adequacy of drug abuse testing services and all other medical services provided by the program.

It is important to realize, however, that guidelines are not binding regulations. Instead, guidelines set forth examples of practices that can satisfy a regulatory requirement—in this case, adequate drug abuse testing. CSAT expects that accreditation bodies will review these guidelines and adopt all or part for inclusion in the accreditation standards they apply to OTPs.

In addition, OTPs should consider that with or without these new guidelines, it remains the medical director’s responsibility to comply in this area and to document the adequacy of any testing approach. Whatever drug abuse test the OTP uses as a part of the accreditation survey, the OTP must be able to support the use of the test with documented evidence showing that the test is adequate.

**Oral Fluid Testing—**A CSAT letter to the field dated July 18, 2003, provides that offsite drug testing using oral fluids may be adequate, at least in some populations, for the purposes of 42 CFR 5 8.12 (f) (6). It is CSAT’s view that sufficient information is now available for medical directors to make a determination of the adequacy of oral fluid testing in the OTP setting.

## **VIII. Miscellaneous**

### **1. Q—What are non-physician health care professionals authorized to do under the regulations?**

**A—**Non-physician health care professionals are permitted to conduct various activities under the regulations. For example, under 42 CFR 8.12 (f), an authorized health care professional under the supervision of the program physician may conduct the required initial physical examination. On the other hand, only a medical director or program physician shall determine a patient’s eligibility for take-home medications under 42 CFR 8.12 (i) (2).

Under the regulations, the medical director and program physicians are responsible for program-wide medication dosing and administration policies. In addition, significant deviations from approved product labeling must be documented by a program physician and medical director (see 42 CFR 8.12 (h) (4)).

However, under 42 CFR (h) (4) (1), practitioners, or agents of practitioners (under the supervision of a practitioner), who are licensed under State law and registered under Federal law, may administer or dispense opioid agonist treatment medications. In some States, physician assistants and nurse practitioners, under the supervision of a physician, are authorized to modify patient medication levels. It is incumbent on the OTP to review and determine State requirements and limitations in this area.

**2. Q—Will these regulatory changes increase treatment capacity?**

**A—**SAMHSA expects that adoption of an accreditation model will increase treatment capacity by making it easier for facilities such as hospitals and health maintenance organizations (HMOs) that are accustomed to meeting accreditation requirements to enter the marketplace. Accreditation and other reforms will make it easier for existing programs to establish relationships with private practitioners. SAMHSA also plans to encourage private physicians to become more active in the treatment of methadone patients.

**3. Q—Will it be cost-effective for individual doctors to treat patients?**

**A—**Yes. Stabilized patients who have been in opioid maintenance treatment for 2 or more years may be eligible for transfer to medical maintenance. Medical maintenance allows these patients increased amounts of take-home medication for unsupervised use and fewer visits to an office-based physician who, in some circumstances, may be away from the clinic site. The office-based physician maintains a formal arrangement with an established OTP that can provide medication, urine-testing services, and any backup social services the patient may need. SAMHSA has issued a letter to the field encouraging programs to pursue this option, which has the potential to expand treatment capacity.

## Appendix D. Standard and Example Forms

### Example of Standard Consent to Opioid Maintenance Treatment

#### CONSENT TO PARTICIPATION IN OPIOID PHARMACOTHERAPY TREATMENT

**Patient's Name:** \_\_\_\_\_

**Date:** \_\_\_\_\_

I hereby authorize and give voluntary consent to the Division and its medical personnel to dispense and administer opioid pharmacotherapy (including methadone or buprenorphine) as part of the treatment of my addiction to opioid drugs. Treatment procedures have been explained to me, and I understand that this will involve my taking the prescribed opioid drug at the schedule determined by the program physician, or his/her designee, in accordance with Federal and State regulations.

It has been explained that, like all other prescription medications, opioid treatment medications can be harmful if not taken as prescribed. I further understand that opioid treatment medications produce dependence and, like most other medications, may produce side effects. Possible side effects, as well as alternative treatments and their risks and benefits, have been explained to me.

I understand that it is important for me to inform any medical provider who may treat me for any medical problem that I am enrolled in an opioid treatment program so that the provider is aware of all the medications I am taking, can provide the best possible care, and can avoid prescribing medications that might affect my opioid pharmacotherapy or my chances of successful recovery from addiction.

I understand that I may withdraw voluntarily from this treatment program and discontinue the use of the medications prescribed at any time. Should I choose this option, I understand I will be offered medically supervised withdrawal.

*For Female Patients of Childbearing Age:* There is no evidence that methadone pharmacotherapy is harmful during pregnancy. If I am or become pregnant, I understand that I should tell my medical provider right away so that I can receive appropriate care and referrals. I understand that there are ways to maximize the healthy course of my pregnancy while I am in opioid pharmacotherapy.

\_\_\_\_\_  
**Signature of Patient**

\_\_\_\_\_  
**Date of Birth**

\_\_\_\_\_  
**Date**

**Witness:** \_\_\_\_\_

Adapted with permission from Department of Psychiatry and Behavioral Sciences, Albert Einstein College of Medicine, Division of Substance Abuse, Bronx, NY.

**Methadone Chain-of-Custody Record**

Date: \_\_\_\_\_

Name of Treatment Program: \_\_\_\_\_

Name of Treatment Program Dispensing Nurse: \_\_\_\_\_

Medication To Be Delivered (Methadone/Suboxone/Subutex):

Number of Doses To Be Delivered:

Medication Provided From \_\_\_\_\_ to \_\_\_\_\_  
 (Date) (Date)

Name of Person Transporting Medication: \_\_\_\_\_

License Number of Person Transporting Medication: \_\_\_\_\_

Date Medication Received: \_\_\_\_\_ Number of doses received: \_\_\_\_\_

Medication Received Covering \_\_\_\_\_ to \_\_\_\_\_  
 (Date) (Date)

COMMENTS:

Signature of person receiving medication

Signature of person transporting medication

**Date of Administration and Initials of Patient Receiving Medication**

<b>DATE</b>	<b>Pt. Initials</b>	<b>DATE</b>	<b>Pt. Initials</b>
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

## **SMA-162 and SMA-168**



DEPARTMENT OF HEALTH AND HUMAN SERVICES SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION CENTER FOR SUBSTANCE ABUSE TREATMENT  Application for Certification to Use Opioid Drugs in a Treatment Program Under 42 CFR § 8.11	Form Approved: OMB Number 0930-0206 Expiration Date: 01/31/2010 See OMB Statement on Reverse DATE OF SUBMISSION
Note: This form is required by 42 CFR 8.11 pursuant to Sec. 303, Controlled Substances Act (21 USC § 823) and the Drug Abuse Prevention and Control Act of 1970 (42 USC § 275(a)). Failure to report may result in a recommendation for the suspension or revocation of the opioid treatment program registration.	
la. NAME OF PROGRAM ( <i>Name of primary dispensing location</i> )  b. Opioid Treatment Program Number (OTP Number): (same as FDA ID)	
c. DEA Registration Number	
2. ADDRESS OF PRIMARY DISPENSING LOCATION ( <i>Include Zip Code</i> )	3. TELEPHONE NUMBER ( <i>Include Area Code</i> ) 4. FAX NUMBER ( <i>Include Area Code</i> ) 5. E-MAIL ADDRESS
6. NAME AND ADDRESS OF PROGRAM SPONSOR ( <i>Include Zip Code</i> )	7. TELEPHONE NUMBER ( <i>Include Area Code</i> ) S. FAX NUMBER ( <i>Include Area Code</i> ) 9. E-MAIL ADDRESS
10. NAME OF MEDICAL DIRECTOR ( <i>and Address—if different than Dispensing Location, above</i> )	11 TELEPHONE NUMBER ( <i>Include Area Code</i> ) 12. FAX NUMBER ( <i>Include Area Code</i> ) 13. E-MAIL ADDRESS
14. PURPOSE OF APPLICATION <input type="checkbox"/> Provisional Certification <input type="checkbox"/> New Sponsor <input type="checkbox"/> New Medical Director <input type="checkbox"/> Relocation <input type="checkbox"/> Medication Unit <input type="checkbox"/> Renewal/Re-certification	
15. NUMBER OF PATIENTS IN TREATMENT ON DATE OF SUBMISSION:  _____ METHADONE                                      _____ LEVO-ALPHA-ACETYL-METHADOL (LAAM)                                      _____ SUBUTEX/SUBOXONE (BUPRENORPHINE)  _____ OTHER (Specify)	
16a. PROGRAM STATUS <input type="checkbox"/> For-profit <input type="checkbox"/> Nonprofit <input type="checkbox"/> Public/Government <input type="checkbox"/> Other ( <i>Specify</i> )	
b. PROGRAM FUNDING SOURCES ( <i>Check each appropriate agency and attach the address of each, if applicable</i> )  <input type="checkbox"/> SAMHSA (Block Grant) <input type="checkbox"/> Private Charities <input type="checkbox"/> Department of Veterans Affairs <input type="checkbox"/> Patient Payment <input type="checkbox"/> State Government <input type="checkbox"/> County Government <input type="checkbox"/> Indian Health Service <input type="checkbox"/> Private Health Insurance <input type="checkbox"/> Other ( <i>Specify</i> ) _____	
17. Application Center for Substance Abuse Treatment Division of Pharmacologic Therapies Substance Abuse and Mental Health Services Administration Attention: OTP Certification Program 1 Choke Cherry Road, Suite 2-1086 Rockville, MD 20857 Overnight: 1 Choke Cherry Road, Suite 2-1086 Rockville, MD 20850  Dear Sir/Madam: As the person responsible for the program (OTP), I submit this application in triplicate for approval to use approved opioid drugs in a program for detoxification and/or maintenance treatment for narcotic addicts in accordance with 42 CFR Part 8, Certification of Opioid Treatment Programs. A copy of this application has been sent to the State Authority within which State the program is located. I understand that SAMHSA and State approvals are necessary to obtain a registration from the Drug Enforcement Administration (DEA).	A. I have a copy of, or access to 42 CFR Part 8, Certification of Opioid Treatment Programs, including 42 CFR § 8.12, the Federal Opioid Treatment Standards. I have read, understand and will comply with these standards which govern the treatment of narcotic addiction with approved opioid drugs.  B. Attached is a description of the current accreditation status of the OTP. This description includes the name and address of the accreditation body and the date of the last accreditation action.  C. Attached is a description of the organizational structure of the OTP which includes the name and complete address of any central administration or larger organizational structure to which this program is responsible. The description shall specify how the program will provide adequate medical, counseling, vocational, educational, and assessment services, at the primary facility, unless the program sponsor has entered into a formal documented agreement with another entity to provide these services to patients enrolled in the OTP. In addition, the attachment includes the names of the persons responsible for the OTP.

FORM SMA-162 (revised January 2007) (FRONT) (*Submit in triplicate*)

<p>D. Attached are the names, addresses, and a description of each hospital, institution, clinical laboratory, or other facility used by this program to provide the necessary medical and rehabilitative services.</p> <p>E. A medical director will be designated to assume responsibility for administering all medical services performed by the program. If a medical director is responsible for more than one program, the feasibility of such an arrangement will be documented and submitted to SAMHSA. Within three weeks of any replacement of the medical director, I shall notify SAMHSA.</p> <p>F. Attached is the address of each medication unit or other facility under control of the OTP. Any new dispensing site for this program, including medication units shall be approved by SAMHSA and the State authority prior to its use. SAMHSA and the State authority shall be notified within three weeks of the deletion of any facility used to dispense opioid treatment drugs.</p> <p>G. A patient records system will be established and maintained to document and monitor patient care in this program. It shall be maintained so as to comply with the Federal and State reporting requirements relevant to narcotic treatment. A drug dispensing record will be maintained to show dates, quantity, and batch or code marks of the drug administered or dispensed, traceable to specific patients. This drug dispensing record must be retained for a period of three years from the date of dispensing.</p> <p>H. I have a copy of or access to 42 CFR Part 2, Confidentiality of Alcohol and Drug Abuse Patient Records. I have read and understand the requirements to maintain the confidentiality of alcohol and drug abuse treatment patient records. I agree to protect the identity of all patients in accordance with the regulations.</p>	<p>I. I shall comply with the security standards for the distribution of controlled substances, as required by 21 CFR § 1301, Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances.</p> <p>J. I agree to comply with the conditions of certification set forth under 42 CFR § 8.11(0). In addition, I shall allow, in accordance with Federal controlled substance laws and Federal confidentiality laws, inspections and surveys by duly authorized employees of SAMHSA, by accreditation bodies, the DEA, and by authorized employees of any relevant State or Federal governmental authority. I agree that OTPs must operate in accordance with Federal opioid treatment standards and accreditation elements.</p> <p>K. I agree to adhere to all rules, directives, and procedures set forth in 42 CFR Part 8, and any regulation regarding the use of an opioid drug for the treatment of narcotic addiction which may be promulgated in the future. I shall inform other individuals who work in this treatment program of the provisions of this regulation, and monitor their activities to assure compliance with the provisions.</p> <p>L. I understand that failure to abide by the rules, directives, and procedures described above may cause a suspension or revocation of approval of my registration by the Drug Enforcement Administration.</p> <p>M. I, as program sponsor, certify that the information submitted in this application is truthful and accurate.</p>
PROGRAM SPONSOR <i>(Signature)</i>	DATE
<p><i>Please send three copies of this form and all attachments to:</i></p> <p>Center for Substance Abuse Treatment                  Division of Pharmacologic Therapies                  Substance Abuse and Mental Health Services Administration                  Attention: OTP Certification Program                  1 Choke Cherry Road, Suite 2-1086                  Rockville, MD 20857</p> <p>Overnight:                  1 Choke Cherry Road, Suite 2-1086                  Rockville, MD 20850</p> <p><i>and two copies to the appropriate State authority.</i></p> <p><i>If submitting this form electronically, please submit electronic copies of all attachments by e-mail to <a href="mailto:olp@samhsa.hhs.gov">olp@samhsa.hhs.gov</a> or submit three copies of all attachments to the mailing address above.</i></p>	
<p>Paperwork Reduction Act Statement</p> <p>Public reporting burden for this collection of information is estimated to average between 6 minutes and 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to SAMHSA Reports Clearance Officer; Paperwork Reduction Project (0930-0206); Suite 7-1043, 1 Choke Cherry Road, Rockville, MD 20857. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0930-0206.</p>	

FORM SMA 162 (revised January 2007) (BACK)

DEPARTMENT OF HEALTH AND HUMAN SERVICES SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION CENTER FOR SUBSTANCE ABUSE TREATMENT  Exception Request and Record of Justification Under 42 CFR § 8.11(h)	Form Approved: OMB Number 0930-0206 Expiration Date: 01/31/2010 See OMB Statement on Reverse  DATE OF SUBMISSION:
Note: This form was created to assist in the interagency review of patient exceptions in opioid treatment programs (OTPs) under 42 CFR § 8.11(h).	
Detailed INSTRUCTIONS are on the cover page of this form. PLEASE complete ALL applicable items on this form. Your cooperation will result in a speedy reply. Thank you.	
Program OTP No: (Same as FDA ID) _____ - <input type="checkbox"/>	Patient ID No: _____
Program Name: _____	
Telephone: _____	Fax: _____ E-mail: _____
Name & Title of Requestor: _____	
Patient's Admission Date: _____	Patient's current dosage level: _____ mg Other: _____
Patient's program attendance schedule per week (Place an "X" next to all days that the patient attends): _____ S _____ M _____ T _____ W _____ T _____ F _____ S *If current attendance is less than once per week, please enter the schedule: _____	
Patient status: _____ Employed _____ Homemaker _____ Student _____ Disabled _____ Other: _____	
Nature of Request: <input type="checkbox"/> Temporary take-home medication <input type="checkbox"/> Temporary change in protocol <input type="checkbox"/> Detoxification exception <input type="checkbox"/> Other: _____	
Decrease regular attendance to (Place an "X" next to appropriate days.): _____ S _____ M _____ T _____ W _____ T _____ F _____ S    Beginning date: _____ *If new attendance is less than once per week, please enter the schedule: _____	
Dates of Exception: From _____ to _____ # of doses needed: _____	
Justification:    Family Emergency    Incarceration    _____ Funeral    _____ Vacation    _____ Transportation Hardship Step/Level Change    Employment    _____ Medical    _____ Facility    _____ Long-Term Care    _____ Other Residential _____ Homebound    Split Dose    _____ Treatment Other: _____	
Regulation Requirements: 1. For take-home medication: Has the patient been informed of the dangers of children ingesting methadone or LAAM?    Yes    No    N/A 2. For take-home medication: Has the program physician determined that the patient meets the 8-point evaluation criteria to determine whether the patient is responsible enough to handle methadone as outlined in 42 CFR § 8.12(i)(2)(i)-(viii)?    Yes    No    N/A 3. For multiple detoxification admissions: Did the physician justify more than 2 detoxification episodes per year and assess the patient for other forms of treatment (include dates of detoxification episodes) as required by 42 CFR § 8.12(e)(4)?    Yes    No    N/A	
Submitted by: Printed Name of Physician _____ Signature of Physician _____ Date _____	
State response to request:    Approved    Denied  State Methadone Authority Date _____	
Federal response to request:    Approved    Denied  Public Health Advisor, center for substance Abuse Treatment Date _____	
Please fax to CSATIDPT at (240) 276-1630 or e-mail: <a href="mailto:otp@samhsa.hhs.gov">otp@samhsa.hhs.gov</a> This exception is contingent upon approval by your State Methadone Authority (as applicable) and may not be implemented until you receive such approval.	

BACKGROUND INFORMATION

FORM SMA-166 (revised January 2007) (FRONT)

**Purpose of Form: This form was created to facilitate the submission and review of patient exceptions under 42 CFR § 8.11(h). This does not preclude other forms of notification.**

**Paperwork Reduction Act Statement**

Public reporting burden for this collection of information is estimated to average 25 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to SAMHSA Reports Clearance Officer; Paperwork Reduction Project (0930-0206); Suite 7-1043, 1 Choke Cherry Road, Rockville, MD 20857. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0930-0206.

FORM SMA-168 (revised January 2007) (BACK)

## Appendix E. Index

### A

accreditation, 1–2, 43  
 application process, 55  
 definition of, 55  
 effect on treatment capacity, 62  
 emergency exception for, 56–57  
 time limits for, 55  
 Accreditation Guidelines  
 expert panel, 1, 50–52  
 FAQs, 54–62  
 meeting observers, 53  
 periodic review of, 2  
 administrative responsibilities, 3–4  
 administrative withdrawal, 21, 43–44  
 admission  
 denial of, 37  
 FAQs, 58  
 patients' rights during, 37, 47  
 admission criteria, 10–11  
 during emergencies, 41–42  
 for pregnant patients, 16  
 15–17  
 for readmission, 20, 59  
 adolescents, care of, 24–25  
 aggressive behavior, 5, 21, 38, 42  
 alcohol abuse, 22, 28, 58  
 alternative therapies, 25–26, 38  
 appeals, 39, 42  
 application process, 54–55, 66–67  
 arrhythmia, medication-induced, 13–14  
 assessment, 13, 43. *See also* diagnosis  
 continuous clinical, 17–19  
 FAQs, 58  
 medication impact, 13, 32–34, 33  
 psychiatric, 14  
 psychosocial, 12–15  
 for take-home medication, 35

### B

barbiturates, 28, 58  
 breastfeeding, 16, 58  
 buprenorphine treatment, 31. *See also*  
 medication-assisted treatment  
 dosage guidelines, 33  
 impact assessment, 13  
 during pregnancy, 15–17

### C

cardiopulmonary resuscitation (CPR), 5  
 Center for Substance Abuse Treatment (CSAT), 1  
 CDC (Centers for Disease Control and Prevention  
 (CDC)), 6, 44  
 certification  
 application process, 54–55, 66–67  
 definition of, 55  
 process of, 1  
 CFR (Code of Federal Regulations), 1, 2, 3  
 Chain- of- Custody Record, 36, 46–47, 64  
 child abuse/neglect, 12, 25  
 childcare services, 25  
 childproof containers, 35, 36, 60  
 clinical environment, management of, 4  
 Code of Federal Regulations (CFR), 1–3  
 communicable diseases. *See also specific disease*  
 counseling on, 27  
 prevention of, 6  
 treatment of, 26  
 community relations, 7–8, 43  
 complaints, 39–40, 42  
 complete blood count (CBC), 15  
 confidentiality of patient records, 2, 4, 12, 14, 19,  
 29–31, 38–39, 42  
 consent. *See* informed consent  
 consultative network, 3  
 Consumer Bill of Rights, 47  
 continuity of care  
 co-occurring disorders and, 27  
 emergencies and, 41  
 medication-assisted treatment and, 36  
 patient discharge and, 21–22  
 for pregnant patients, 15–17, 16  
 upon patient transfer, 14, 19  
 upon program closure, 8  
 continuous clinical assessment, 17–19  
 continuous quality improvement, 5–8, 42  
 controlled substances, diversion control plan for,  
 8–9, 34, 36, 46, 57  
 co-occurring disorders  
 maintenance therapy and, 33  
 management of, 15, 22, 27  
 co-occurring pain, 23–24, 42, 44, 59  
 counseling services, 26–27  
 family, 44  
 HIV, 27, 44  
 credentials, staff, 9–10, 43

criminal justice issues, 25  
 critical incidents, 6–7  
 CSAT (Center for Substance Abuse Treatment),  
 1 cultural competency, 24, 37, 38, 47

**D**

detoxification. *See* medically supervised  
 withdrawal  
 diagnosis. *See also* assessment  
 HIV, 17, 23  
 opioid addiction, 11, 13–15, 43  
 opioid dependence, 10–11, 13–15, 42–43  
 diagnostic criteria, 14–15  
 directly observed therapy (DOT), 27  
 disaster plans, 5, 41–42  
 discharge, 21  
 continuity of care and, 21–22  
 medically supervised withdrawal and, 20  
 during pregnancy, 17  
 displaced patients, 41–42  
 not currently in treatment, 42  
 treated by pain clinics, 42, 59  
 disruptive conduct, 5, 21, 38, 42  
 diversion control plan (DCP), 8–9, 34–, 36, 46,  
 57  
 documentation, 29–31  
 during emergencies, 41–42  
 of patients' rights and responsibilities, 36–37  
 dosage guidelines, 32–33, 41, 44, 60  
 dose caps, 32, 59  
 Drug Addiction Treatment Act (DATA) (2000),  
 32, 42  
 drug screening tests, 11, 14–15, 28, 58, 61  
 DSM-IV-TR, 10, 11, 14  
 duration of treatment, 18–19, 33, 43–44

**E**

electrocardiogram (EKG), 13, 15  
 emergencies, program, 5, 35, 41–42  
 emergency contact system, 5  
 emergency exception, from accreditation, 56–57  
 emergency services, access to, 38  
 emergency treatment, medication-assisted, 18, 56  
 employment data, 3–4, 9–10  
 environmental codes, 4  
 ethics, professional, 42  
 evaluation, 13, 43  
 of patient progress, 17–19, 43  
 Exception Request, 41, 45, 68–69

**F**

facility environment, management of, 4  
 family history, 14  
 family involvement, 44  
 family needs, 25, 44  
 FAQs (frequently asked questions), 54–62  
 FDA  
 Adverse Event Reporting Program, 7  
 "Consent to Methadone Treatment" form, 59  
 drug approvals, 31  
 FDA number, 54  
 Federal Food, Drug, and Cosmetic Act, 31  
 fees, nonpayment of, 21  
 Federal Food, Drug, and Cosmetic Act, 31  
 fees, nonpayment of, 21  
 female patients. *See also* pregnant patients  
 general principles regarding, 25  
 Food and Drug Administration (FDA)  
 Adverse Event Reporting Program, 7  
 "Consent to Methadone Treatment" form, 59  
 drug approvals, 31  
 FDA number, 54  
 forms  
 informed consent, 39, 59, 63  
 methadone chain of custody, 36, 46–47, 64  
 SMA-162, 54–55, 66–67  
 SMA-168, 41, 45, 68–69

**G**

goals of treatment, 3, 32–33  
 Good Guideline Practices, 2  
 grievance process, 39–40, 42  
 guest dosing, 19, 41, 45–46

**H**

health care provider. *See also* physician  
 nonphysician, authority of, 61–62  
 patient's choice of, 37–38  
 hepatitis, viral, 23  
 HIPAA, 14, 27, 39  
 HIV infection  
 counseling on, 15, 26–27, 44  
 management of, 23 in  
 pregnant patients, 17  
 testing for, 15, 23  
 homebound patients, medication dispensing for,  
 46–47  
 hours of service, 4, 37, 41, 57  
 human resources management, 3–4  
 Hurricane Katrina, 41

**I**

identification, patient, 41  
 incarceration, 21, 25, 46  
   medication dispensing and, 46–47  
 incident reporting, 6–7, 39, 42  
 individualized treatment plan, 38  
 infection control, 6  
 information disclosure, 36–37, 41  
 informed consent, 11–12, 30, 36–37, 42  
   emergencies and, 41  
   by pregnant patients, 16, 58, 63  
   standardized form for, 59, 63  
 initial medical examination services, 12–15, 43, 58  
 initial medical examination services, 12–15, 43, 58  
 intensity of treatment, 18  
 involuntary program closure, 8

**J**

job descriptions, 3, 9

**L**

Levo-alpha-acetyl methadol (LAAM) treatment, 31, 33, 58, 59  
   state authority to prohibit, 60–61  
 life safety issues, 5  
 locked containers, medication storage in, 46, 60

**M**

maintenance therapy, 33  
   accreditation/certification for, 56  
   patient admission criteria for, 10–11  
 medical assessment, 12–15, 43, 58  
 medical director  
   authority of, 61–62  
   definition of, 3  
   replacement of, notification of, 3, 4, 54, 55  
   responsibilities of, 3, 4  
 medical history taking, 14  
 medical laboratory evaluation, 14–15, 43  
 medically compromised patients, medication dispensing for, 46–47  
 medically supervised withdrawal, 19–20, 43–44  
   dosage principles, 32, 60  
   emergency plan for, 41–42, 56  
   FAQs, 56–57  
   against medical advice, 20  
   pain management during, 23–24, 42, 44  
   during pregnancy, 16, 20  
   in stages of treatment, 18

  support of, 20  
   take-home medication during, 57  
 medication-assisted treatment. *See also specific agent*  
   administration of, 31–34  
   dosage guidelines, 32–33, 41, 44, 60  
   duration of, 18–19, 33, 44  
   FAQs, 59–60  
   goals of, 32–33  
   guest dosing, 19, 41, 45–46  
   impact assessment, 13, 33  
   legal limits on, 32  
   medically supervised withdrawal from, 19–20  
   monitoring of, 34  
   outside prescriptions and, 45  
   patient education about, 37  
   for pregnant patients, 15–17, 58  
   schedule for, 37  
   side effects of, 13–14  
   stages of, 18  
   unsupervised (*See take-home medication*)  
 medication dispensing, 301–34  
   for co-occurring disorders, 27  
   diversion control plan for, 8–9, 34–, 36, 46, 57  
   documentation of, 30–31  
   emergency plan for, 5, 35–36, 41, 56  
   FAQs, 59  
   legal limits on, 32  
   physician authority for, 35, 44, 61–62  
   for take-home use, 34–36, 46–47, 57  
 medication errors, prevention of, 5  
 medication formulations, 34, 59  
 medication security, 36, 46–47  
 medication storage  
   documentation of, 30  
   in locked containers, 46, 60  
 medication unit, new, application for, 55 MedWatch, 7  
 mental health needs, 22  
 methadone treatment, 31. *See also medication-assisted treatment*  
   accreditation/certification standards, 56  
   breastfeeding during, 16, 58  
   Chain- of- Custody Record, 36, 46–47, 64  
   dispensing guidelines, 31–32, 59  
   dosage guidelines, 33, 44, 60  
   emergency plan for, 41, 42  
   impact assessment, 13  
   patient transfer and, 36  
   during pregnancy, 15–17, 58, 63  
   state authority to prohibit, 60–61

- multidrug abuse, 22, 33, 58  
 multiple program enrollments, avoiding, 31  
 mutual-help groups, 27
- N**
- Narcotic Addiction Treatment Act, 42  
 neonatal abstinence syndrome, 17  
 noncompliance, dosing guidelines and, 33  
 nondiscrimination policies, 24, 37, 38, 47
- O**
- office-based physician, treatment provided by,  
     cost-effectiveness of, 62  
 Office of National Drug Control Policy  
     Reauthorization Act (2006), 32  
 opioid addiction  
     diagnosis of, 11, 13–15, 43  
 opioid addiction  
     duration of treatment for, 18–19, 33, 44  
     natural history of, treatment considerations  
         related to, 17–18  
 opioid agonists. *See* medication-assisted  
     treatment; *specific agent*  
 opioid dependence, diagnosis of, 10–11, 13–15,  
     43  
 opioid treatment program (OTP)  
     definition of, 56  
     standards for (*See* accreditation; certification)  
     without accreditation, emergency exception  
         for, 56–57  
 opioid use history  
     admission on basis of, 11  
     maintenance dosage guidelines and, 33  
 oral fluid testing, 61  
 organizational structure, 3–4  
 orientation programs, 26–27, 37, 44, 47  
 outcome measures, 6  
 outside prescriptions, 45  
 over-the-counter counter (OTC) medications, 13,  
     33, 37, 45
- P**
- pain clinics, displaced patients from, 42, 59  
 pain management, 23–24, 42, 44, 59  
 parenting skills services, 25  
 patient abuse, reporting of, 39, 42  
 patient admission. *See* admission  
 patient complaints, 39–40, 42  
 patient compliance  
     dosing guidelines and, 33–34  
     take-home medication and, 35  
 patient deaths, reporting, 7  
 patient discharge. *See* discharge  
 patient education, during orientation, 26–27, 37,  
     44, 47  
 patient identification, 41  
 patient participation, in treatment decisions, 38,  
     40  
 patient records, 29  
     confidentiality of, 2, 4, 12, 14, 19, 29–31,  
         38–39, 42  
     upon program closure, 8  
 patient relocations, voluntary, 19  
 patient responsibilities, 40, 47  
 patient rights, 36–40, 47  
 patient satisfaction surveys, 6  
 patient-to-staff ratio, 10, 27, 38, 43  
 patient transfer, 14, 19, 36  
 personnel files, 3–4, 9  
 pharmacotherapy. *See* medication-assisted  
     treatment; *specific agent*  
 physical evaluation, 12–15, 43, 58  
 physician  
     individual, treatment provided by, cost-  
         effectiveness of, 62  
     prescribing limits for, 32  
 physician authority, 61–62  
     importance of, 3, 43  
     for medication dosage, 44  
     for take-home medication, 35  
 plan, patient's choice of, 37–38  
 postpartum patients, special services  
     for, 15–17, 43  
 pregnant patients  
     administrative withdrawal of, 21  
     Federal regulations concerning, 11  
     HIV infection in, 17  
     medically supervised withdrawal in, 16, 20  
     medication use in, 15–17, 58, 63  
     special services for, 15–17, 43  
 primary care, 15, 22, 27  
 privacy, patient, 2, 4, 12, 14, 19, 29–31, 38–39,  
     42, 47  
 product labeling, opioid agonists, 32, 33  
 program changes, notification of, 3, 4, 54  
     time limit for, 55  
 program closure, 8  
 program director  
     definition of, 4  
     responsibilities of, 4  
 program emergencies, 5, 35, 41–42



program enrollment. *See also* admission criteria  
 multiple, avoiding, 31  
 program policies, review of, 6  
 program responsibilities, for patients' rights, 36  
 program sponsor  
 definition of, 3, 55  
 replacement of, notification of, 3, 54, 55  
 responsibilities of, 4  
 program transfers,  
 program update form, 54  
 provisional certification, definition of, 55  
 psychiatric assessment, 14, 43  
 psychosocial assessment, 12–15, 43  
 public health interest, conditions of, 26, 27

## Q

QT interval, 14, 15  
 quality assurance programs, 5–8, 42  
 diversion control plan in, 8–9, 34, 36, 46, 57

## R

readmission, 20, 59  
 recordkeeping, 29–31, 44  
 Record of Justification, 45, 68–69  
 referrals, 14  
 administrative withdrawal and, 21  
 network for, 3  
 patient choice and, 37  
 for pregnant patients, 16  
 refusal of treatment  
 medically supervised withdrawal and, 20  
 by pregnant patients, 16  
 research projects and, 38  
 registration, emergency, 56  
 relapse prevention, 19, 43  
 continuity of care and, 21–22  
 medically supervised withdrawal and, 20  
 patient participation in, 40  
 reporting, incident, 7, 39, 42  
 Request-for-Exception process, 41, 45, 68–69  
 required services, 12–15  
 research projects, informed consent for, 37  
 residential treatment, temporary, 46  
 respect for patients, 38  
 resuscitation, 5  
 retention in treatment, 19, 43  
 risk management, 5  
 risk reduction education, 27

## S

safety issues, 5  
 SAMHSA, 1–2  
 emergency guidelines, 41  
 program update form, 54  
 Substance Abuse Treatment Facility Locator, 41  
 SAMHSA number, 54  
 screening, 11–15, 58, 61  
 security issues, 5  
 medication, 36, 46–47  
 self-help groups, 27  
 sentinel events, 6–7  
 sexually transmitted disease (STD), 14, 26, 27  
 SMA-162 application process, 54–55, 66–67  
 SMA-168 form, 41, 45, 47, 68–69  
 smoking cessation, 23  
 staff  
 credentials of, 9–10, 43  
 violence toward, 5, 38  
 staff development, 6, 9, 43  
 staff-to-patient ratio, 10, 27, 38, 43  
 standing orders, 11, 43  
 state authority, to prohibit opioid agonist  
 treatment programs, 60–61  
 State Methadone Authorities (SMAs), 41, 55  
 state-specific questions, 60–61  
 Suboxone, 32, 35  
 substance abuse  
 co-occurring, 22, 33, 58  
 counseling, 27  
 testing services, 15, 28–29, 58, 61  
 Substance Abuse and Mental Health Services  
 Administration (SAMHSA), 1–2  
 and drug testing, 58  
 emergency guidelines, 41–42  
 program update form, 54  
 regulations, 58  
 reporting to, 4, 42  
 SAMHSA number, 54  
 SMA-162 application process, 54–55, 66–67  
 SMA-168 form, 41, 45, 47, 68–69  
 Substance Abuse Treatment Facility Locator,  
 41  
 Subutex, 32, 35

**T**

take-home medication, 34–36  
  dispensing guidelines, 34–36, 46–47, 57  
  emergency plan for, 41  
  exception request for, 41, 45, 68–69  
  during medically supervised withdrawal, 57  
  monitoring of, 36, 46  
  patient eligibility for, 57  
  patients' rights and, 36  
  state-specific regulations, 60  
tapering, 11, 19, 42, 43. *See also* medically supervised withdrawal  
temporary residential treatment, 46  
30-patient limit, 32  
3-day emergency exception, 56–57  
torsades de pointes, 13–14  
toxicology testing, 15, 28–29, 58, 61  
traveling patients, medication for, 19, 36, 41  
treatment  
  FAQs, 58–59  
  intensity and duration of, 18–19, 33, 43–44  
  medication-assisted (*See* medication-assisted treatment)  
  patient's choice of, 37–38  
treatment capacity, effect of accreditation guidelines on, 62  
Treatment Improvement Protocol (TIP), 1, 18, 22, 29, 35, 44, 58  
treatment planning, 17–19  
treatment progress, evaluation of, 17–19, 43  
triage, 14  
tuberculosis (TB), 15, 26, 27  
twelve-step groups, 20, 27

**U**

unsupervised medication. *See* take-home medication  
urine specimen testing  
  alternatives to, 61  
  collection for, 28

**V**

violence, 5, 12, 21, 38, 42  
viral hepatitis, 23  
voluntary patient relocations, 19  
voluntary program closure, 8

**W**

waivered physicians, 32  
withdrawal  
  administrative, 21, 43  
  medically supervised (*See* medically supervised withdrawal)  
withdrawal syndrome  
  dosing guidelines and, 33  
  neonatal, 17  
women  
  care of, in treatment, 25  
  violence against, 12  
Workplace Standards, 28

Area	Standard Number	Standard
Assess the Environment	A. Leadership	1.Organization identified its structure, roles and responsibilities of each level of leadership
		2.Identified Leadership guides the following: mission, promotion of value and achievement of outcomes in programs, compliance with insurance risk management, financial solvency, corporate responsibility, legal and regulatory requirements
		3. Responds to the diversity of its stakeholders with respect to culture, age, gender, sexual orientation, socioeconomic status, language
		4.Corporate responsibility efforts include the following: code of ethics in at least the following areas; business, marketing, service delivery, professional responsibilities, human resources, written procedures to deal wit allegations of violations of ethical codes, education of personnel and other stakeholders on ethical codes of conduct
		6. When organization is governed by a board, it recruits board members who are representative of the specific culture the organization services, population, population being served
		7.organization has a written plan on cultural competency an diversity that includes the recruitment of persons who are representative of the specific cultures the organization serves for: leadership, management, direct services support positions
		8. Organization leadership annually reviews the organization’s policies, assume final authority over and responsibility for the accountability of the programs, is accessible to the persons served, personnel
		9. organization conducts or participate in the public education or activities which promote the elimination for the persons served, advocates for the needs of the persons served
	B. Governance	1.Board has governance policies that facilitate ethical governance practices, assure stakeholders, that governance is active in the organization, meet the legal requirements of governance.
		2. Governance policies and practices include policies on the selection and composition of the board including board membership criteria, selection process, member orientation, board education and development, exit process, selection of board and committee chairs, policies on board structure, size, composition, definition of independent unrelated board representation, financial matters between the organization and individual board membership, compensation, loans, expense reimbursement, stock ownership, use of external advisors including external auditors, executive compensation advisors, annual self assessment of the board, periodic assessment of individual members, annual signed code of ethics, external links with outside parties
		3. Board’s relationship with executive leadership includes: delegation of authority, access to management and

		staff, support of governance of organization
		4. Board processes including agenda planning, developing and distribution of board materials, overseeing the following committee work; governance development and management, financial audit, executive compensation, other
		5. Governance policies address executive leadership develop and evaluation including formal annual written review of executive leadership performance in relation to overall organization performance
		7. Governance policies address executive compensation including written statement of total executive compensation philosophy, base pay, incentive plans, benefits plans
		8. Governing Body annual reviews its governance policies
	C. Strategic Integrated Planning	1. Ongoing strategic planning of the organization considers; expectation of persons served, expectations of other stakeholders, competitive environment, financial opportunities and threats, organizations capabilities, service areas needs demographics, regulatory and legislative environments
		2. Written strategic plan including current and projected financial position, goals, priorities, implementation strategy and is share with persons served, other stakeholders, reviewed annually and updated for relevance
	D. Input from persons served and other stakeholders	1. Organization demonstrates that it obtains input on an ongoing basis from persons served, personnel, other stakeholders using a variety of mechanisms
		2. Leadership analyzes input and uses it in program planning, performance improvement, strategic planning, organizational advocacy. financial and resource planning
	E. Legal Requirements	1. Organization demonstrates a process to comply with the following legal and regulatory requirements: rights of persons served, confidentiality requirements, reporting, contractual, licensing, corporate status, employment practices, privacy of persons served, debt covenants
		2. Organization implements written procedures to guide personnel in responding to subpoenas, search warrants, investigations, other legal actions
	F. Financial Planning and Management	1. Organization's financial planning and management activities are designed to meet established outcomes for the persons served and organization performance objectives
		2. Budgets are prepared that including reasonable projections of revenues and expenses, input from various stakeholders comparison to historical performance and are disseminated to appropriate personnel and others and written
		3. Actual financial results are compared to budget and reported to various personnel and stakeholders, reviewed quarterly
		4. Organization identified and reviews at a minimum revenues and expenses, internal and external financial

		trends, financial challenges and opportunities, business trends, management information, financial solvency with the development of remediation plans if appropriate
		5. If organization is a subsidiary of a parent entity it identifies financial reliance on related entities and legal and other responsibilities between related entire organization
		6. Organization establishes and maintains fiscal policies and procedures including internal control practice, provides initial and ongoing training on billing and coding procedures for personnel
		7. If the organization bills for services provided, a review of a representative sampling of records of the persons served is conducted at least quarterly to document that dates of services provided coincide with billed episodes of care, determine that the bills accurately reflect the services that were provided identify necessary corrective action
		8. The organization, if responsible for fee structures identifies the basis of the fee structure, demonstrates the review of the fee schedules, modifications when necessary, disclosure to the persons served of all fees for which they will be responsible
		9. Evidence of an annual review of audit of the financial statements of the organization conducted by an independent certified public accountant, chartered accountant or similar accountant
		10. If the review or audit generates a management letter, the organization provides the letter during the survey and provides evidence of correction of material matters or reasons why they will not be corrected
		11. If the organization takes responsibility for the funds of persons served, it implements written procedures that define, how the person served will give informed consent for the expenditure of the funds, how persons served will access the records of their funds, how funds will be segregated for accounting purposes, safeguards in place to ensure that funds are used for the designated and appropriate purposes and how interest will be credited to the accounts of the persons served
	G. Risk Management	1. organization implements a risk management plan that includes id of loss exposures, evaluation and analysis of loss exposures, id of how to rectify exposures, implementation of actions to reduce risk, reporting results of actions taken to reduce risk, inclusion of risk reduction in performance improvement activities
		2. As a part of risk management, the insurance package of the organization is reviewed for adequacy on an annual basis, protects assets, and includes property coverage, liability coverage and other coverage as appropriate
	H. Health and Safety	1. Organization maintains a healthy and safe environment
		2. Organization has written procedures to promote the safety of persons served, personnel
		3. Persons served receive information and training designed to reduce identified physical risks
		4. Personnel receive competency-based training upon hire, annually, in the following areas of health and safety practice, id of unsafe environmental factors, emergency procedures, evacuation procedures, ID of critical

		incidents, reporting of critical incidents, medication management if appropriate, reducing physical risks and is documented
		5. Written emergency procedures for fires, bomb threats, natural disasters, utility failures, medical emergencies, safety during violent or other threatening situation that satisfy the requirements of applicable authorities, practices appropriate for the locale and addresses the following: evacuation when appropriate from the complete facility, safety of evacuees, accounting for all persons involved, temporary shelter when applicable, id of essential services, continuation of essential services, emergency phone numbers, notification of appropriate emergency authorities
		6. Immediate access to first aid expertise, first air equipment and supplies, relevant emergency information on the persons served and personnel
		7. Organization has written procedures regarding critical incidents that include prevention, reporting, remedial action, medication errors, use of seclusion and restraints, incidents involving injury, communicable disease, infection control, violence and aggression, use of possession of weapons, elopement and wandering, vehicular accidents, biohazardous accidents, unauthorized use or possession of licit or illicit substances, abuse and neglect, other sentinel events
		8. Written analysis of all critical incidents is provided to or conducted by the leadership at least annually and addresses the following: causes, trends, actions for improvement, results of performance improvement plans
		9. Organization implements infection control activities that include the training regarding the prevention and control of infections and communicable diseases for persons served, personnel, appropriate use of standard or universal precautions by personnel
		10. Organization's transportation services, including self assessment demonstrating compliance with all applicable legal and regulatory requirements, appropriate licensing of all drivers, review of driving records of all drivers on an ongoing basis, insurance covering vehicles and passengers, safety feature in vehicles, safety equipment, accessibility, training of drivers in the organization transportation requirements, written emergency procedures, communication devices, road warning/hazard equipment, first aid supplies, maintenance of vehicles owner or operated according to manufacturers recommendations, if services are contracted; annual review of the contract against elements listed above, knowledge by rivers of unique needs of persons served.
		11. Comprehensive health and safety inspections are conducted at least annually, by a qualified external authority, result in a written report that identifies the areas inspected, recommendations for areas needing improvement, actions taken to respond to the recommendations
		12. Comprehensive health and safety inspections are conducted at least semi-annually on each shift and result in a written report that identifies the areas inspected, areas needing improvement and actions taken to respond to the recommendations
		13. Unannounced test of all emergency procedures are conducted at least annually on each shift and include

		complete actual or simulated physical evacuation drills, are analyzed for performance improvement, result in improvement of or affirm satisfactory current practice and are evidence in writing
		14. Organization identifies personnel responsible for implementing the health and safety plans and procedures
		15. In congregate-setting residential programs, external inspections include review by a fire authority at least once every two years
		16. There is equipment and training appropriate to the needs of the persons served and personnel for fire detection, warning of fire hazard, suppression of fires
		17. System for reporting critical incidents provides for documentation of timely debriefings conducted following emergency situations
		18. Written procedures that provide for safe handling , storage and disposal of hazardous materials
		19. Organization implements policies and procedures that address the handling of items brought into the program by the persons served or personnel including illegal drugs, legal drugs, prescription medication and weapons
		20. Organization implements its written policy regarding the use of tobacco products in all locations, vehicles owned or operated by the organization
		21. All vehicles that are owned or operated by the organization, and used to provide transportation for the persons served contain secured first aid supplies and secured fire suppression equipment
	I.Human Resources	1. There are an adequate number of personnel to meet the established outcomes of the persons served, ensure the safety of persons served, deal with unplanned absences of personnel and meet the performance expectations of the organization
		2. Written procedures identify required credentials of personnel, background of personnel, if required in the following areas; criminal checks, immunizations, fingerprinting, drug testing, required credential remain current, prior to the delivery of services to the persons served or to the organization, throughout employment in response to the information needed
		3. The organization demonstrates recruitment and retention efforts, ID of any trends in personnel turnover
		4. Identifies the skills and characteristics needed by personnel to assist the persons served in the accomplishment of their established outcomes, support eh organization in the accomplishment of its mission and goals, assess the current knowledge and competencies of personnel at least annually, provides the resources to personnel for learning and growth
		5. Performance management includes job descriptions that are reviewed and/or updated annually, promotion guidelines, job posting guidelines,
		6. If students or volunteers are used by the organization, the following are in place: a signed agreement, id of duties, scope, supervision, orientation and trainings, assessment of performance, confidentiality practices, policies and written procedures of dismissal, background checks

		7. Personnel policies are established and maintained, accessible to applicable personnel, grievance and appeal procedures for all personnel, hiring practices, nondiscrimination in areas of employment, compensation, assignment of work, promotion reviewed annually and updated as needed
		8. Organization ensures that the individuals on the team provide services consistent with relevant state legislation governing practices, licensure reqs, registration reqs, certification reqs educational degrees, professional training, on-the job training requirements, professional standards of practice
		9. Procedures to verify required credentials for all applicable personnel provide for initial verification of credentials with primary sources
		10. Records for personnel contain, at a minimum, employment app or resume, verification of credentials, evidence of orientation, performance evaluation reports, criminal background checks, other info as required by law
		11. Initial training and ongoing training updates for all personnel including the rights of the persons served, person and family center services, prevention and work place violence, confidentiality requirements, cultural competency, expectations regarding professional conduct.
	J. Technology	1. Organization implements a technology and system plan that includes the following: hardware, software, security, confidentiality, back up policies, assistive technology, disaster recovery preparedness, virus protection, support information management and performance improvement activities
		2. If the organization provides services via the internet, the organization provides for the following: security of personal info, alternative access formats, accessibility and accommodations, user-friendly interface, online info 24/7, personnel to provide instruction and guidance to accessing services provided by the organization
		3. The organization assess its use of technology to enhance individual services and improve the efficiency and productivity of personnel
	K. Rights of persons served	1. the rights of persons served are communicated in a way that is meaningful, prior to the beginning of service delivery, annually for persons served in a program that is longer than 1 year, available at all times for review and clarification
		2. Organization implements policies promoting the following rights of the persons served including confidentiality of info, privacy, freedom from abuse, financial or other exploitation, retaliation, humiliation neglect
		3. The organization implements a policy by which persons served may formally complain to the organization, is in writing and specifies that the action will not result in retaliation, explains how efforts will be made to resolve the complaint and includes levels of review which include the availability of external review, timeframes, procedures to address the complaint, rights and responsibilities of each party, availability of advocates or other assistance, readily available to the persons served, understandable to the persons served
		4. Review of formal complaints is conducted annually and determines trends, areas needing performance improvement actions to be taken



		5. Organization's policies promoting the rights of the persons served address: methods by which the person served may review his or her record, use of crisis intervention procedures, written procedures governing the use of special treatment interventions and restrictions of rights, methods to ensure the intrusive procedures are administered in a safe manner
		6. In order to promote maximum integration and inclusion of the persons served, the organization demonstrates a process of regularly evaluating any restrictions placed on the rights or privileges of the persons served, methods to reinstate restricted or lost privileges and rights
		7. Appropriate safeguards are implemented to protect the records of the persons served, confidential administrative records
		8. Appropriate safeguards of records include organization of records in a systemic fashion, designation of one or more staff members who have responsibility for controlling the records,
		9. Organization implements policies and procedures regarding information to be transmitted to other individuals or agencies
	L. Accessibility	1. The leadership demonstrates accessibility planning that addresses the needs of the persons served
		2. Accessibility plan(s) address the following areas: architecture, environment, attitudes, finances, employment, communication, transportation, community integration when appropriate,
		3. Accessibility status report about the removal of barriers and is prepared annually, is in writing and includes the progress to be made in the removal of identified barriers, areas needing improvement
		4. Requests for reasonable accommodation are identified, reviewed, decided upon and documented
	M. Information measurement and Management	1. Data are collected that provide info on the needs of the persons served, needs of other stakeholders, business needs of the organization, allow for comparative analysis
		2. Organization demonstrates how it addresses data and its reliability, validity, completeness and accuracy
		3. For business function improvement the organization sets performance indicators, measures performance indicators, utilizes the following data: financial, resource allocation, surveys, risk analysis, human resources, technology analysis environmental health and safety
		4. Service delivery improvement the data collection system includes the characteristics of the persons served, collects data on persons served at the beginning of services, appropriate intervals, the end of services, and points in time following services; measures the effectiveness of services, the efficiency of services and service access
	N. Performance Improvement	1. Analysis is completed at least annually, analyzes performance indicators in relation to performance goals, business functions, service delivery of each program seeking accreditation, efficiency and access
		2. Information is used to review the implementation of the mission and core values of the organization, improve the quality of services and programs, facilitate organizational decision making and strategic planning

		3. Performance information is shared in formats that are useful to the persons served, personnel and other stakeholders
	O. General Program Standards	1. Each Core Program for which the organization is seeking accreditation has a written plan that guides the delivery of services and includes a description, philosophy, goals description of the service modalities, ID of special populations and mechanisms to address their needs, assurance that adequate resources are available to deliver the identified core programs
		2. Program's choice of service approaches is based on accepted practice in the field and is supported by one or more of the following: research, evidence-based practices, field recognition or published practice guidelines
		3. Services are designed and implemented to support the recovery, health or well-being of the persons or families served, enhance the quality of life of the persons served, reduce the symptoms or needs and build resilience, restore or improve functioning, support the integration of the persons served into the community
		4. Organization determines competency and provides and/or arranges for competency-based training to personnel providing direct services in the following: areas that reflect special needs of persons served, clinical skills appropriate to the position, individual plan development, interviewing skills, program related research-based treatment approaches
		5. Program receives appropriate medical consultation regarding medical related policies or procedures
		6. In a medically supervised program, there is a medical director who is a physician
		7. The program offers one or more of the following: provision of peer support, local advocacy groups, consumer/survivor/ex-patient groups, self help groups, other avenues of support
		8. Program ensures that information and education that is relevant to the needs of the persons served is provided
		9. As appropriate, families are encouraged to participate in educational programs offered, invited to participate in clinical programs with persons served with consent or legal right, procedures are established that provide for coordination and ongoing communication between internal and external service providers,
		10. Written procedures specify that the program provides or arranges for crisis intervention services
		11. Written procedures specify the program provides or arranges for crisis intervention
		12. Team members, in response to the needs of the persons served help empower each person served to actively participate with the team to promote recovery, progress or well-being
		13. Documented ongoing supervision of clinical or direct service personnel addresses accuracy of assessment and referral skills, appropriateness of treatment or service intervention selected relative to the specific needs of each person served, treatment service effectiveness, provision of feedback that enhances the skills of direct service personnel, issues of ethics, legal aspects of clinical practice and professional standards, clinical documentation issues, cultural competency issues

		14. When applicable, there are policies and supporting written procedures that address positive approaches to behavioral interventions including an emphasis on building positive relationships with persons served, evaluation of the environment, appropriate interaction with staff to promote de-escalation, manage behaviors, empower persons served to manage their own behavior, and development of a personal safety plan for each person served on an individual basis
	b. Screening and Access to Services	1. Written and procedures define access to services
		2. Clearly written admission and readmission criteria are established, are used and include how admissions will be prioritized, who is responsible for making the admission decisions, exclusionary or ineligibility criteria
		3. When Screening is conducted by the organization it includes a review of each person's eligibility for admission based on the person's presenting problem, need for services, legal eligibility criteria, assesses for the appropriateness of available services, availability of funding sources, id whether the organization can provide the services needed, including an interview with the person to be served or referral source, ID and documentation of immediate and urgent needs of the person served, when appropriate, a pre-admission, on-site visit to the organization and its programs by the person to be served/legal guardian, ensures that screening tools are uniformly administered, personnel are trained on the use of the tool prior to administration
		4. When a person is found ineligible for services, the person is informed as to the reasons, referral source is informed of the reasons, recommendations are made for alternative services or disposition, and documentation of actions are maintained
		5. If a waiting list is maintained; written procedures are in place, info documents the person's needs, length of time on the list, maintains a current list through a continual review and update, contact with the persons on the list based upon each person's needs, documentation of any and all contacts on the list, procedures for referral to necessary care including medical and crisis care are developed for persons on the list, list info is used to assist in an organizations planning process
	Orientation	6.Each person served receives an orientation that is appropriate to his or her needs and the type of services provided
	Assessment	7.Assessments are conducted by qualified personnel including knowledgeable to assess the specific needs of the persons served and trained in the use of applicable tools
		8. Assessments include information obtained from the person served, family members/legal guardians, other collateral sources
		9. Primary Assessment process gathers sufficient information to develop an individualized person centered plan for each person served, including information about the person's presenting problems, urgent needs including

		suicide risk, personal strengths, individualized needs, interest and abilities, preferences, previous behavioral health services including diagnostic info, treatment information, medication use profile, efficacy of current or previously used medications, medication allergies, physical health history, diagnosis, co-occurring disabilities, disorders or medical concerns, mental status, pertinent current and historical life situation information including the following: age, gender, employment history, legal involvement, family history, history of abuse/neglect, violence, relationships including natural supports, issues important to the persons served
		10. Assessment results in the preparation of an interpretive summary that is based upon the assessment data, used in the development of the individual plan, identifies any co-occurring disabilities
		11. Ongoing assessment process focuses on the person's specific needs, identifies the needs and expectations of the person service is responsive to the changing needs of the persons served includes provisions for communicating the results of the assessment to personnel, legal/guardian, others as appropriate
		12. Reassessments are conducted within time frames established by the organizations or external regulatory reqs., following significant life status changes of the person served
	Individual Plan	1 & 2. The individual plan is developed with the active participation of the person served. The plan is prepared using information from the assessment and interpretive summary, is based upon the needs of the persons served and focuses on their integration and inclusion into the local community, family when appropriate, natural support systems, needed services, involves the family/legal guardian, identifies any needs beyond the scope of the program, specifies the services to be provided, specifies referrals for additional services, communicated to the person in a manner that is understandable
		3. Individual plan includes the following: goals expressed in the words of the person served, reflective of the informed choice of the person, appropriate to the person's culture, appropriate to the person's age, based upon the person's strengths, needs, abilities, preferences, specific treatment objectives, reflective of the person's development, culture, responsive to the person's disability, understandable to the person measurable, achievable, time specific appropriate to the treatment setting, ID of specific treatment interventions to be used, frequency of treatment transition to other community services, legal requirements, legally imposed fees, a personal safety plan, triggers, including an assessment of the risk for dangerous behaviors, current coping skills, warning signs, preferred interventions advance directives
		4. when person has co-occurring disabilities and/or disorders: the plan should address those issues in an integrated manner, services are to be provided by personnel who are qualified to provide for co-occurring disabilities and disorders
		6. Individual plans are reviewed periodically with the person served for relevance, modified when needed
		7. Signed and dated progress notes document, achievement of identified objectives, goals, significant events or changes in the life of the person served, delivery of services and specific interventions that support the plan, movement to other levels of care

		8. Designated individuals assists in the coordinating services for each person served by assuming responsibility for plan implementation, promoting participation of person served on an ongoing basis, ID and addressing gaps in service provision, sharing of information on how to access community resources relevant to his or her needs, advocacy, communicating info regarding progress, facilitating transition between service levels and types, involving family or legal guardian, coordinating services provided outside of the organization, identifying the after-hours contact
	Transition and Discharge	1. Written transition and discharge criteria are established and used
		2. Based on the needs of the persons served, in order to support ongoing recovery, treatment/service gains or increased community inclusion, the program follows its procedures for referrals, transition to other services, discharge
		3. When clinically indicated, transition planning is initiated with the person served at the earliest possible point in the individual planning and service delivery process.
		4. As appropriate, persons served have options to move to community-integrated settings
		5. The written transition plan is prepared or updated to ensure a seamless transition when a person serve is transferred to another level of care, another components of care, an aftercare program or prepares for planned discharge.
		6. Documents provided to external programs/services to support a person's transition plan include the person's identified: strengths, needs, abilities, preferences
		7. Individuals who participate in the development of the transition plan receive copies of the plan, when permitted
		8. When the transition plan indicates the need for additional services of supports, personnel are identified who will be responsible for follow-up after transition to: maintain the continuity and coordination of needed service, determine with the person served whether further services are needed, offer to refer to needed services, when possible
		9. When an unplanned transition or discharge occurs, personnel are identified who will be responsible, for follow-up to determine with the person served whether further services are needed, offer or refer to needed services when possible
		10. When person is discharged or removed from a program for aggressive and/or assaultive behavior, follow-up occurs to ensure linkage to appropriate care, within 72 hours post discharge,
		11. For all persons leaving services, a written discharge summary is prepared to ensure that the person served has documented treatment episodes and results of treatment..discharge summary must include the following: date of admission, describes services provides, presenting condition, extent to which goals were achieved, status of person served at last contact, recommendations for services or supports, date of discharge from the program

	E. Medication Use	1. Organization has a policy that identifies whether medications are used in the program, process person served to obtain medications needed to promote recovery and/r desired treatment outcomes, prescribing, dispensing, administering
		2. In response to the needs of the persons served and the type of service, documented ongoing training and education regarding medications is received by the persons served, personnel providing direct service to the person served including how the medication works, risks, intended benefits, side effects, contraindications, potential implications between medications and diet/exercise, risks associated with pregnancy, importance of taking medications as prescribed, need for lab monitoring, early signs of relapse, signs of non adherence to medication prescriptions,
		3. When organization physically controls medications, written procedures including compliance with all applicable regulations pertaining to medications and controlled substances, including on-site pharmacy and dispensing, purchasing, transportation, safe storage, safe handling, packaging and labeling, management of biohazards, safe disposal inventory, self administration, off-site use
		4. When medications are prescribed for or provided to a person served an up to date individual record of all medications, including non-prescription and non psychoactive medications
		5. Organization that provides prescribing, dispensing, or administering of medications implements written procedures that include compliance with all applicable laws and regulations, active involvement of the persons served in making decisions related to the use of medications, availability of a physician, pharmacist, or qualified professional licensed to prescribe for consultation 24/7 days/week, documentation and reporting.etc
		6. Organization that provides prescribing of medications has written procedures that include screening for common medical co-morbidities, evaluation of co-existing medical conditions, for potential medication impact, identifying potential drug interactions, documentation or confirmation of informed consent for each medication prescribed continuing a prescribed medication if a generic medication is not available, continuity of medication use when identified as a need in a transition plan for a person served
		7. An organization that provides prescribing of medications demonstrates the use of treatment guidelines and protocols, promotes state of the art prescribing, ensure safety of person served, utilizes evaluation, which includes measures of effectiveness, satisfaction of persons served
		8. In an organization that prescribes medications, a documented peer review is conducted at least annually, on a representative sample of records for whom prescriptions were provided
		9. The Peer Review process reports results to all applicable staff, process is used to improve the quality of services provided, incorporated into the organization's performance improvement system
		10. In an organization that prescribes medications, written procedures address staff credentials and competencies, documentation of medication administration errors and reactions, use and benefits of as needed (prn) doses, coordination when a medication is prescribed by a source other than the organization

	Non-Violent Practices	1.Has a policy that identifies how it will respond to aggressive or assaultive behaviors, whether and under what circumstances seclusion and restraints are used within the programs it provides
		2. All direct service or front line personnel employee by the organization receive documented initial and ongoing competency-based training in threatening behaviors including training on recovery and trauma-focused services and the use of personal safety plans
		3. All personnel involved in seclusion and restraints receive documented initial and ongoing competency-based training, provided by persons or entities qualified to conduct such training on how and when to restrain or seclude, recognition of signs of physical distress in the person who is being restrained
		4. A plan is implemented to minimize or eliminate the use of restraints and/or seclusion that includes identification of the leader, use of data to inform the practice, development of workforce attitudes, skills and practices, that support recovery, specific strategies to prevent crisis
		5. Written status report on the plan for minimization or elimination of the use of seclusion and/or restraint and is prepared annually, includes goals and timelines, progress made, areas needing improvement
		6. Written procedures for the use of specific interventions for adults, children and adolescents, persons with special needs, team interventions include defining the team leadership, assigning team duties
		7. If a personal safety plan exists for the person served it is readily available for immediate reference
		8. Organization that uses seclusion or restraint has policies that specify that all attempts will be made to de-escalate crisis, and is administered by behavioral health personnel who are trained and competent in the proper techniques
	Records of persons served	1. Individual record communicates information in a manner that is organized, clear, complete, current, legible
		2. all documents require signatures including original or electronic signatures
		3. Individual record includes date of admission, info about the persons personal representative, emergency contact, person coordinating services of the person served, location of any other record, primary healthcare physician, health reimbursement info, person's history, current medications, preadmission screening, documentation of orientation, assessments, individual plan, transition plan, discharge summary, correspondence pertinent to the person served, authorization of releases, documentation of internal and external referrals
		4. Entries to the records follow the organization's policy that specifies time frames for entries
		5. If duplicate information or reports from the main record of a person served exist, or if working files are maintained such materials are not substituted for the original record and are considered secondary documents
	H. Quality records review	1. Organization conducts or participates in at least quarterly review of the services provided. Review process addresses the quality of services as evidenced in the record, appropriateness of the services, patterns of service utilization reviewed quarterly by personnel who are trained and qualified on a representative sample of current and closed records

Core Program Standards	A. Day Treatment	1-8. Program is available at least 4 days/week, at least 3 hours/day and is directed by a qualified behavioral health practitioner. Majority of program hours consist of schedule treatment activities, including at least three of the following: aoda education, , family therapy or counseling, provision of or lineage with vocational activities, group psychotherapy or counseling, individual psychotherapy, medication education, assistance with daily living, assistance with accessing community supports, occupational therapy. Program has consistently assigned personnel, has consistently scheduled activities, provides assessment and diagnostic services, medication monitoring and program is provided by a multi-disciplinary team.
		9. When persons served have psychiatric needs, psychiatric services are available to the persons served, include the availability of a psychiatrist 24/7
		10. Referral is made to alternative services when medically indicated, clinically indicated
	b. Detoxification	1. Criteria for admission are consistent with those outlines in the definition of Opioid dependence in the current edition of the DSM
		2. A physical evaluation is fully documented before admission to the detox program
		3. Policies and procedures are in place to ensure that each person served provides written informed consent for services prior to the receipt of such services
		4. Organization has written procedures that address co-existing health issues including mental health problem, use and abuse of licit and illicit drugs or alcohol, hepatitis, HIV or other sexually transmitted diseases, infectious diseases, pregnancy and prenatal care
		5. When appropriate, the organization has cooperative agreements with the criminal justice system to encourage continuous detox services to persons who are
		6. Organization has policies and procedures for providing detox services to persons prior to their incarceration
		7. A physician or designee directly supervised by the physician, provides onsite, medical supervision and oversight of the detox program
		8. For persons involved in detox for six months or less, the program provides frequent and sufficient contact with each person served to monitor his/her progress toward treatment goals
		9. Organization has a policy that addresses the impact of detox services, (including accelerated withdrawal) on persons with co-occurring disorders , health needs
		10. When providing detox services to women the program provides respectful and safe treatment, provides counseling regarding specific women's issues, domestic violence, sexual abuse, reproductive health issues, assigns counselors and specialized groups based on the needs of women served, desires of women served
		11. When providing services to pregnancy women the program adheres to accepted medical standards during pregnancy including Opioid dependence etc..
		12. When providing detox services to pregnant women whose withdrawal symptoms cannot be eliminated, referrals to medical programs are made





**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.

*AADD*—abuse/addiction disease/disorder.

*Abuse*—any act or failure to act that caused or may have caused injury to a client knowingly, recklessly, or intentionally, including incitement to act. Injury may include, but is not limited to: physical injury, mental disorientation, or emotional harm, whether it is caused by physical action or verbal statement.

*Adequate/Sufficient*—reasonable, enough, e.g., personnel to meet the needs of the clients currently enrolled in a specific program.

*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).

*Adolescent*—an individual between the ages of 13 and 17 inclusive who has not been emancipated by marriage or judicial decree. Incarcerated adolescents will be in accordance with incarceration guidelines.

*Advertise*—to solicit or induce to purchase the services provided by a treatment facility.

*Adult*—an individual 18 years of age or older, or an individual under the age of 18 who has been emancipated by marriage or judicial decree. Persons aged 16 and above may voluntarily seek and receive substance abuse services without parental consent.

*At Risk*—identification by the Office for Addictive Disorders (OAD) of greater potential for the use/abuse of alcohol and other drugs.

*ATOD*—alcohol, tobacco, and other drugs.

*Board(s)*—entities responsible for licensure/certification for specific professions (e.g., nursing, counselors, social workers, physicians, etc.). State of Louisiana boards are the only accepted credentialing organizations for all personnel.

*Client/Patient/Consumer/Participant*—any person assigned or accepted for prevention or treatment services furnished by a licensed facility as specified.

*Compulsive Gambling*—persistent and recurrent maladaptive gambling behavior that disrupts personal, family, community, or vocational pursuits, and is so designated by a court, or diagnosed by a licensed physician, licensed social worker, licensed psychologist, licensed professional counselor, or advanced practice registered nurse who is certified in mental health.

*Consultation*—professional oversight, advice, or services provided under contract.

*Core Functions*—the essential and necessary elements required of every abuse/addiction treatment facility.

a. *Assessment*—core function in which a counselor/program identifies and evaluates an individual's strengths, weaknesses, problems, and needs for the development of the treatment plan.

b. *Case Management*—core function in which services, agencies, resources, or people are brought together within a planned framework of action toward the achievement of established goals. It may involve liaison activities and collateral contacts with other providers/facilities.

c. *Client Education*—core function in which information is provided to individuals and groups concerning alcoholism and other drug abuse, positive lifestyle changes, and the available services and resources.

d. *Client Orientation*—core function in which the client is informed regarding:

i. general nature and goals of the program;

ii. rules governing client conduct and infractions that can lead to disciplinary action or discharge from the program;

iii. availability of services;

iv. costs; and

v. client's rights.

e. *Consultation with Professionals*—core function in which functional relationship with counselors and other credentialed health care professionals is provided as required to assure comprehensive quality care for the client.

f. *Counseling (Individual/Group) Services*—core function in which appropriate support is provided to the client by those professionals qualified to provide therapeutic services. Special skills are used to assist individuals, families, or groups in achieving objectives through:

i. exploration of a problem and its ramifications;

ii. examination of attitudes and feelings;

iii. consideration of alternative solutions; and

iv. decision making and problem solving.

g. *Crisis Intervention Services*—core function in which appropriate assistance is rendered during emergencies, including 24-hour telephone coverage by a qualified counselor, to provide:

i. telephone assistance to prevent relapse;

ii. referral to other services; and

iii. support during related crises.

h. *Intake*—core function in which information is gathered about a prospective client. Information is given to a prospective client about the treatment facility and facility's treatment and services.

i. *Referral*—core function in which appropriate services not provided by the facility are identified, and client/family is assisted to optimally utilize the available support systems and community resources.

j. *Reports and Record Keeping*—core functions in which results of the assessment and treatment planning are recorded. Written reports, progress notes, client data, discharge summaries and other client-related documentation is recorded in the client record.

k. *Screening*—core function in which the determination is made as to whether a client meets the

program's admission criteria. Information such as the person's reason for admission, medical and substance abuse history, and other needed information, is used to determine client's need for treatment, and/or appropriateness of admission.

1. *Treatment Planning*—core function in which the counselor and the client:

- i. identify and rank problems needing resolution;
- ii. establish agreed upon immediate objectives and long-term goals; and
- iii. decide on a treatment process, frequency, and the resources to be utilized.

*Core Requirements*—as contained in this Chapter apply to all facilities licensed to provide substance abuse prevention, treatment, or detoxification. Sections 7401 - 7425 contain core requirements for all facilities and §7427 - §7457 contain additional requirements that apply to specific programs.

*Counselor*—qualified professional (QPS or QPC) as described in this document.

*Counselor in Training (CIT)*—a person currently registered with Louisiana State Board Certified Substance Abuse Counselor (LSBCSAC) Board and pursuing a course of training in substance abuse counseling including educational hours, practicum hours, and direct, on-site supervision of work experience hours by a facility-employed QPS/QPC.

*Department*—the Louisiana Department of Health and Hospitals (DHH). The following is a list of pertinent sections:

a. Health Standards Section (HSS)—Section of Bureau of Health Services Financing, DHH that surveys, licenses, and serves as the regulatory body for health care facilities in the state.

b. Office for Addictive Disorders (OAD)—DHH office responsible for providing treatment and prevention services related to abuse/addiction disease/disorders.

c. Office of Public Health (OPH)—DHH Office that establishes and enforces various legislative health codes.

d. Office of Planning and Review (OPR)—DHH office which professionally reviews all floor plans and site plans prior to licensing to assure compliance with state laws and codes.

e. Program Integrity Section (PRS)—Section of Bureau of Health Services Financing, DHH responsible for investigating fraud and abuse.

*Diagnosis*—the act of identifying a disease (AA/DD) by a qualified licensed professional (licensed professional counselor, physician, social worker, advanced practice registered nurse, or psychologist) based on comprehensive assessment of physical evidence [if related to diagnosis], signs and symptoms, clinical and psychosocial evidence, and client/family history.

*Doctorate-Prepared*—an individual who has completed a Doctorate in social work, psychology, or counseling, but has not met the requirements for licensing by the appropriate state board.

*Exploitation*—act or process to use (either directly or indirectly) the labor or resources of a client for monetary or personal benefit, profit, or gain of another individual or organization.

*Facility*—provider of services, including all employees, consultants, managers, owners, and volunteers as well as premises and activities.

*Joint Ventures*—facilities funded/operated by both public and private sources. Joint ventures are classified as private entities.

*LSBCSAC*—Louisiana State Board Certified Substance Abuse Counselor.

*Masters-Prepared*—an individual who has completed a Masters Degree in social work or counseling, but has not met the requirements for licensing by the appropriate state board.

*Medication Administration*—preparation and giving of legally prescribed individual dose to client; observation and monitoring of client/client response to medication.

*Medication Dispensing*—compounding, packaging, and/or giving of legally prescribed multiple doses to client.

*Medication-Prescription (Legend)*—medication that requires an order from a licensed practitioner and that can only be dispensed by a pharmacist on the order of a licensed practitioner and requires labeling in accordance with R.S. 37:1161 et seq.

*Medication-Nonprescription*—medication which can be purchased over-the-counter without a licensed practitioner's order.

*Minor*—any person under the age of 18.

*Office of State Fire Marshal (OSFM)* □ establishes and enforces various legislative building codes.

*Off-Site Operation*—either autonomous or semi-autonomous, that is related to parent facility and located in same or adjacent parish.

*On Call*—immediately available for telephone consultation and less than one hour from ability to be on duty.

*On Duty*—scheduled, present, and awake at the site to perform job duties.

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

*Primary Prevention*—focus on reducing the onset of incidences (rate of occurrences) of alcohol, tobacco, and other drug (ATOD) use by non-users, preventing the development of ATOD use problems, and enhancing individual strengths as an inoculant against ATOD use.

*Program*—a specific group of therapeutic services designed to deliver treatment/prevention to a defined client population.

*Public*—owned and operated by federal, state, or local government.

*Sexual Exploitation*—a pattern, practice, or scheme of conduct that can reasonably be construed as being for the purpose of sexual arousal or gratification or sexual abuse of any person.

*Site/Premises*—a single identifiable geographical location owned, leased, or controlled by a facility where any element of treatment is offered or provided. Multiple buildings may be contained in the license only if they are connected by walk-ways and not separated by public street or have different geographical addresses.

*Staff*—individuals who provide services for the facility in exchange for money or other compensation, including employees, contract providers, and consultants.

*Standards*—policies, procedures, rules, and other guidelines (i.e., standards of current practice) contained in this Chapter for the licensing and operation of substance abuse/addiction treatment facilities.

*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.

*Substance Abuse/Addiction Treatment/Prevention Facility*—any facility which presents itself to the public as a provider of services related to prevention and/or treatment of the abuse/addiction of controlled dangerous substances, drugs or inhalants, alcohol, problem or compulsive gambling, or a combination of the above. Facility shall be licensed to provide treatment to clients diagnosed with abuse/addiction disease/disorders (AADD) and provide support and prevention intervention to families, the public, and to those individuals identified as having greater than normal risk for developing abuse/addiction disease/disorders.

*Supervision*—occupational oversight, responsibility and control over employee(s)/service delivery by critically watching, monitoring, and providing direction.

*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. *Treatment Level*—a group of treatments/services designed to positively impact a specific type/degree of abuse/addiction.

*Unethical Conduct*—conduct prohibited by the ethical standards adopted by DHH, state or national professional organizations or by a state licensing agency.

*Unprofessional Conduct*—any act or omission that violates commonly accepted standards of behavior for individuals or organizations.

*Variance or Waiver*—administrative decision by HSS or DHH secretary or designated personnel qualified to make the decision that failure (for limited time period), to meet a Minimum Standard cannot potentially cause harm to any client/citizen or interfere with quality treatment. Facility shall post all variances/waivers in conspicuous place.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1057.1 - 9, redesignated 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. General. Any facility which presents itself to the public as a provider of services related to the prevention and/or treatment for abuse/addiction of controlled dangerous substances, drugs or inhalants, alcohol, problem or compulsive gambling, or a combination of the above is required to have a valid and current license prior to admitting any client.

B. Compliance. Each licensed facility must comply with the minimum requirements in order to remain licensed. In

addition, each facility is required to have a copy of the minimum standards on-site, and all administrative and professional staff should be familiar with contents of this rule.

#### C. Exemptions

1. Hospitals, nursing homes, and federally-owned facilities are exempt from licensure.

2. State facilities are exempt from the following general requirements:

- a. licensure fees;
- b. budgetary/audit requirements;
- c. disclosure of ownership forms;
- d. planning, location requirements;
- e. governing body regulations; and
- f. liability insurance.

3. The Department of Health and Human Services, Substance Abuse and Mental Health Services Administration (SAMHSA) promulgated a rule requiring that all Opioid 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. Adherence Requirements. Each facility shall adhere to requirements throughout the period of licensure. Any period of non-compliance may result in sanctions, denials, or corrective action.

E. Variance. Any variance granted by HSS shall:

1. be in writing;
2. cannot be retroactive;
3. be granted for a specific period of time, but less than one year; and
4. be listed on the facility license.

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.

1. Additional locations shall operate in the same or adjacent parish and shall meet the following conditions:

- a. OSFM/OPH approval;
- b. adequate professional staff to comply with all standards;
- c. adequate administrative and support staff to comply with all standards;
- d. personnel records may be housed at parent facility;
- e. client records may be housed at parent facility;
- f. telephone system to forward calls to parent facility;
- g. initial survey is required prior to opening, but annual/renewal survey may be by attestation;

2. License to operate at off-site location will be issued from HSS when the following criteria are met:

- a. adequate professional staff to operate at two or more locations;
- b. identified need for services by OAD; and
- c. submission of request for opening off-site and completed application and payment of applicable fees.

3. Treatment services shall be equal at all locations, however, off-site facilities may refer clients to parent facility to supplement core functions only when client is not expected to endure excessive expense or hardship to obtain required services.

4. Twenty-four hour off-site facilities shall meet and maintain compliance with all requirements for which the facility license is issued.

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

1. Twenty-Four-Hour Facilities. (May be designated for adults, adolescent, or parents/dependent children.)

- a. Detoxification Facilities
  - i. Medically Supported
  - ii. Non-medical (Social)
- b. Primary Treatment Facilities
  - i. In-patient Treatment
  - ii. Residential Treatment
- c. Community-Based Treatment Facilities
  - i. Halfway House
  - ii. Three Quarter House
  - iii. Therapeutic Community (Long Term

Residential)

2. Outpatient Facilities
  - a. Outpatient Counseling
  - b. Intensive Outpatient Treatment
  - c. Opiate Addiction Treatment
3. Additional Designations (conjointly approved by OAD/HSS in writing)
  - a. Youth Based Programs
  - b. Community Education Only

H. Services. The services shall be provided in accordance with license designation.

1. Any additional services provided on the premises shall be identifiable to the public as separate and apart from the licensed program.

2. Clients/families must be notified in writing upon admission when client will be housed in any building not covered in the license issued by DHH/HSS.

I. License Types.

1. Full. A full license is issued only to those agencies that are in compliance with the minimum standards and all

other licensure requirements. The license is valid until the date of expiration unless revoked or suspended prior to the date of expiration, or denied renewal.

2. Provisional. A provisional license is issued to those facilities that are not in compliance with the minimum standards when the termination of a license will occur if systemic changes fail to correct identified problems, provided that cited deficiencies are not detrimental to the health and safety of clients. A provisional license is valid for six months or until a designated termination date. Any license involved in an appeal process is automatically considered provisional.

J. Display of License. The current license shall be displayed on-site at each facility in full view of all clients and/or visitors. Any license issued by DHH supersedes previously issued licenses issued for the facility to operate under this chapter and deems those previously issued as invalid. Any facility displaying and/or using an invalid or altered license will be sanctioned.

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.

1. Change of Ownership

a. Include a copy of bill of sale, licensure fee, disclosure of ownership form, new application form, and information about relocation, name change, etc.

b. License is nontransferrable; new owners must apply for a new license.

2. New Construction and Renovations. All plans must have prior approval of the Office for State Fire Marshal and DHH Office of Planning and Review.

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.

4. Change of Services. An application packet appropriate to the new service is required. An initial survey may be required prior to issuance of new license at the discretion of HSS.

5. Hours of Operation. Written approval by HSS is required in advance of the change.

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

L. Cessation of Business. If at any time the facility decides to cease operations then the facility is responsible for surrendering the license and notifying HSS of the date of

cessation of services and the permanent location of the records.

1. All active clients and pertinent information shall be transferred/referred to appropriate treatment facilities.

2. Written notification with license shall be sent to HSS within five working days.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1057.1 - 9, redesignated 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 26:1453 (July 2000), LR 31:669 (March 2005).

#### **§7405. Fees**

A. General. All fees must be submitted to DHH in the form of a company or certified check or money order, and is to be made payable to the Department of Health and Hospitals (DHH). All fees are nonrefundable and nontransferable.

1. Fee Amounts. The current fee schedule is available upon request.

2. Initial Application. The fee for the initial application process and initial licensure shall be submitted prior to consideration of the license application.

3. Annual Renewal. The fee is payable in advance of issuance of a renewal license.

4. Change Fees. A fee must accompany any request requiring the issuance of a replacement license.

B. Late Fees. Any fee for renewal, or any other fee, is delinquent after the due date and an additional fee shall be assessed beginning on the day after the date due. No license will be issued until all applicable fees are paid.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1057.1 - 9, redesignated R.S. 40:1058.1 - 9.

HISTORICAL NOTE: Promulgated by 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 26:1454 (July 2000).

#### **§7407. Initial Licensure**

A. Application Procedure. This process assures that the facility is capable of organizing, planning and carrying out an operation to provide the 12 core functions of counseling and other therapeutic services as designated on license. The entire application process must be completed within 90 days from the date of the original submission of the application in order to be approved. A completed application packet shall contain:

1. letter of intent that includes:
  - a. proposed date of operation;
  - b. program mission;
  - c. program description;

2. written Plan of Professional Services including a list of the 12 core functions of AA/DD treatment and a facility plan to furnish those services.

3. current application, disclosure forms and other forms with application fee.

4. written approval from the Office of Planning and Review for the proposed facility, if required.

5. a letter-size sketch of the floor plan.

6. jurisdictional approvals as required by:

- a. Office of Public Health;
- b. Office of State Fire Marshal;
- c. municipal zoning and other approvals as applicable;
- d. others, if necessary, (e.g., State Methadone Authority);

7. proof of general and professional liability insurance of at least \$500,000.

8. governing body information including names, addresses, telephone numbers of each member;

9. disclosure in writing of any financial and/or familial relationship with any other entity receiving third-party payor funds, or any entity which has previously been licensed in Louisiana;

10. organizational chart for all professional level personnel.

B. Exceptions. If a requirement is not applicable to the program being licensed, the applicant may list and mark "not applicable." HSS can assist by telephone, if additional answers are needed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1057.1 - 9, redesignated R.S. 40:1058.1 - 9.

HISTORICAL NOTE: Promulgated by 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 26:1455 (July 2000).

#### **§7409. Survey**

A. General

1. All surveys shall be unannounced and may be in conjunction with other agency personnel and/or personnel from other local, state or federal agencies.

2. Any facility that cannot be surveyed when scheduled will be sanctioned unless prior arrangements are approved by HSS and will not be licensed until all fines are paid.

B. Initial

1. On-site survey of all aspects of the operation is required prior to the admission of any client for treatment at the facility.

2. DHH shall determine whether the facility is capable of becoming operational as indicated by compliance with all accepted standards of completed preparations and employment of all personnel, as well as securing all jurisdictional approvals.

3. Facility must become fully prepared for survey within six months of completion of application process.

4. Facility shall be staffed to admit clients and all personnel shall have received orientation.

5. Facility shall be fully prepared to begin admitting clients before requesting an on-site survey.

6. Facility shall meet all requirements of the Minimum Standards.

a. If survey findings indicate that facility has minor violations, a corrective plan of action shall be submitted before issuance of a license.

b. All client oriented corrections shall be completed before DHH issues a license.

c. All unlicensed direct care workers must have criminal history checks with appropriate action taken prior to initial survey.

7. Any facility that is not recommended for licensure following the on-site survey shall be required to submit another application fee and application packet for review prior to requesting a subsequent on-site survey.

8. No client may be admitted until the survey has been completed and facility has been notified that it is approved to admit clients. Health Standards surveyor shall notify the facility verbally as to whether it is appropriate to begin admitting clients or to await further direction by DHH.

C. Annual Survey. An on-site survey of all aspects of the facility is performed annually to assure and promote continuous adherence to standards.

D. Complaint Investigations. DHH shall determine the type and extent of investigation to be made in response to complaints in accordance with R.S. 40: 2009.13 et seq.

1. May be an internal investigation with a report submitted to DHH/HSS.

2. May be on-site focused or complete survey by DHH/OAD and/or DHH/HSS and other local, federal, and state agencies as appropriate.

E. Follow-up Surveys. On-site visit, or request for submission of documentation for desk review to assure that corrective actions have been completed as alleged in the submitted plan of corrections and/or to assure continued compliance between surveys.

F. Survey Results. All survey results become available for public inspection 60 days after the survey or on the date that an acceptable plan of correction is received from the facility, whichever is sooner. If violations of Minimum Standards are:

1. minor and do not directly involve client care, the facility may be allowed up to 60 days to make all necessary corrections;

2. not minor or if they directly affect client care, adverse action shall be implemented.

G. Plan of Corrections. Written allegations of correction are submitted from facility to HSS to describe actions taken by the facility in response to cited violations.

1. Required Components/Elements

a. Actions taken to correct any problems caused by deficient practice directed to a specific client.

b. Actions taken to identify other clients who may also have been affected by deficient practice, and to assure that corrective action will have positive impact for all clients.

c. Systemic changes made to insure that deficient practice will not recur.

d. Quality assurance plan developed to monitor to prevent recurrence.

2. Miscellaneous

a. All components of the corrective action plan must be specific and realistic, including the dates of completion.

b. Plan must be submitted as directed by HSS staff, usually within 10 days of the date of the survey, or the provider may be sanctioned.

c. Corrections must be completed within 60 days of survey unless directed to correct in less time due to danger or potential danger to clients/staff.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1057.1 - 9, redesignated R.S. 40:1058.1 - 9.

HISTORICAL NOTE: Promulgated by 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 26:1455 (July 2000).

**§7411. Annual License Renewal**

A. License must be renewed at least annually. It is the responsibility of the facility to:

1. request a renewal packet from HSS if one is not received at least 45 days prior to license expiration;

2. complete all forms and return to HSS at least 30 days prior to license expiration;

3. submit annual licensure fee, if required, with renewal packet; and

4. submit proof of insurance with renewal packet.

B. Annual license renewal for Primary Prevention programs may be accomplished by attestation provided that:

1. the facility has had three consecutive years of deficiency-free surveys, and

2. Office for Addictive Disorders recommends attestation in writing.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1057.1 - 9, redesignated R.S. 40:1058.1 - 9.

HISTORICAL NOTE: Promulgated by 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).

**§7413. Adverse Actions**

A. General. DHH reserves the right to suspend, deny (initial or renewal), or revoke any license at the discretion of the secretary or his/her designee. Facility owners and staff shall be referred to other entities, such as boards or state or federal enforcement agencies, when there is suspicion of illegal, unprofessional or unethical behavior. Any involuntary termination of licensure or voluntary termination to avoid adverse action automatically disqualifies that facility and those associated with the facility from applying for licensure for a period of at least one year.

B. Denial of Initial License. Denial of initial licensure shall be in accordance with R.S. 40:1058.5(A). Additionally, DHH shall not accept application for an additional facility with common owners, managers, or staff unless the original facility is in full compliance for one year without interruption and is not under investigation by any other agency.

C. Revocation or Denial of Renewal of License. License may be revoked or denied for the following nonexclusive reasons: [See also R.S. 40:1058.5(B)]

1. cruelty or indifference to the welfare of the clients;

2. misappropriation or conversion of the property of the clients;

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

a. serving more clients in the facility than authorized by license;

b. repeated failure to adhere to rules and regulations that resulted in issuance of a provisional license or other sanction;

c. serious violation of standards or current professional standards of practice;

d. failure to submit corrective action plans for identified violations;

e. reasonable cause to suspect that client health/safety is jeopardized;

f. reliable evidence that the facility:

i. falsified records;

ii. failed to provide optimum therapy in accordance with current standards of practice; or

iii. has bribed, solicited or harassed any person to use the services of any particular facility;

g. failure to submit required fees in a timely manner;

h. failure to cooperate with survey/investigation by DHH/authorized agencies;

i. failure to employ and utilize qualified professionals;

4. permitting, aiding, or abetting the unlawful, illicit, or unauthorized use of drugs or alcohol within the facility;

5. conviction or plea of nolle contendere by the applicant for a felony. If the applicant is an agency, the head of that agency must be free of such conviction. If a subordinate employee is convicted of a felony, the matter must be handled administratively to the satisfaction of HSS.

6. documented information of past or present conduct or practices of the facility which are detrimental to the welfare of the clients.

D. Provisional License. As described in § 7403.

E. Appeals.

1. Notice. HHS shall give at least 30 days notice of denial of renewal or revocation of license unless DHH determines that the health and/or safety of clients is in jeopardy. In the event that DHH determines that the health and/or safety of clients is in jeopardy, clients will be removed from the facility immediately. No advance notice will be provided when health and/or safety are involved, and the facility may appeal within 30 days following the removal.

2. Administrative Reconsideration. Request must be submitted in writing to HSS (designee of DHH secretary) within 15 days of receipt of the notice of denial of renewal or revocation.

3. Administrative Appeal. Request must be submitted in writing to DHH, Office of the Secretary within 30 days of receipt of the notice of denial of renewal or revocation. Request for administrative reconsideration does not affect time frames for requesting administrative appeal.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1057.1 - 9, redesignated 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 B. Core Requirements for All Programs §7417. Organization and Administration**

### **A. Administration Quality and Adequacy**

1. Facility administration shall be qualified and adequate to assure adherence to all licensing standards.

2. Qualifications shall be determined by the complexity of the services being provided.

3. Facility compliance with licensing standards shall determine adequacy of available administrative oversight.

4. Facilities shall be organized so that administrative personnel do not perform any programmatic duties and/or make clinical decisions, unless licensed/certified to make clinical decisions.

B. Administrative Records. Record keeping shall be in accordance with accepted standards to assure the development and implementation of facility specific policies and procedures to adhere to all licensing standards.

1. Personnel (staff providing direct care to clients)

a. Annual health screens in accordance with OPH guidelines (includes Dietary workers when applicable).

b. Actual hours of work

c. Orientation/training/in-services

d. Disciplinary actions

e. Results of criminal background checks on all direct care staff

f. Verification of professional credentials, licensure/certification and renewals

g. Job descriptions/Performance expectations

2. Administrative Operations

a. Organizational chart

b. Mission and description of services

c. Payment methods in accordance with Wage and Hour Board

d. Proof of general and professional liability insurance in the amount of at least \$500,000

e. Projected plan of operations based on the findings of the facility specific to continuous improvement program

f. Written agreements with other entities to assure adherence to licensing standards and continuity of care

g. Written designation of facility administrator and clinical services director. Facility may have other job titles as desired, however, the above two positions are required for each facility.

3. Governing Body. All private providers shall have an identifiable governing body composed of adults who have legal authority over the policies and activities of the facility. Responsibilities include:

a. governing of all facility operations;

b. documentation to identify all members including name, address, telephone numbers with current updates as indicated;

c. maintenance of written minutes of all meetings of the governing body, including, but not limited to, date, time, location, participants, topics discussed, decisions reached, and actions taken, committee reports, and any other pertinent information;

d. annual documented review and appropriate actions on all policies, procedures, facility rules, goals, grievances, budget, internal and external evaluations, (including all survey findings);

e. codes of conduct to ensure professional, ethical and legal operations;



f. facility practices that ensure employees have necessary administrative support to provide therapeutic milieu for clients.

C. Ownership. Type of ownership must be identified.

1. Public  government entities (local, state, and federal)

2. Private  for profit or nonprofit

- a. individual
- b. corporation (individual, group of individuals, or publicly-owned stock)
- c. church
- d. council/organization
- e. joint ventures/contractors

D. Facility Protocols. Each facility shall establish facility-specific, written policy and implement such policy in these areas.

1. General

- a. Procedures to ensure the health, safety, and well-being of clients.
- b. Procedures to ensure that clients receive optimum treatment in order to achieve recovery.
- c. Criteria to assure access to care without over-utilization of services.
- d. Protocols to assure uniform and quality assessment, diagnosis, evaluation, and referral to appropriate level of care.
- e. Procedures to assure operational capability and compliance.
- f. Procedures to assure that only qualified personnel are providing care within the scope of the core functions of substance abuse treatment.
- g. Procedures to assure that delivery of services shall be cost-effective and in conformity with current standards of practice.
- h. Procedures to assure confidentiality of client records.

2. Continuous Quality Improvement Program (CQIP). Facility shall:

- a. have ongoing programs to assure that the overall function of the clinic is in compliance with federal, state, and local laws, and is meeting the needs of the citizens of the area, as well as attaining the goals and objectives developed from the mission statement established by the facility;
- b. focus on improving patient outcomes and patient satisfaction;
- c. have objective measures to allow tracking of performance over time to ensure that improvements are sustained;
- d. develop/adopt quality indicators that are predictive of desired outcomes or are outcomes that can be measured, analyzed and tracked;
- e. identify its own measure of performance for the activities it identifies as priorities in quality assessment and performance improvement strategy;
- f. conduct distinct successful improvement activities proportionately to the scope and complexity of the clinic operations;
- g. immediately correct problems that are identified through its quality assessment and improvement program that actually or potentially affect the health and safety of the clients;
- h. make an aggressive and continuous effort to improve overall performance of clinic and personnel;

i. use the process of improvement (identification of client care and service components; application of performance measures; and continuous use of a method of data collection and evaluation) to identify or trigger further opportunities for improvement; and

j. use annual internal evaluation procedure to collect necessary data to formulate plan and quarterly meetings of staff committee (at least three individuals) to assess and choose which CQIP activities are necessary and set goals for the quarter, to evaluate the activities of the previous quarter, and to implement immediately any changes that would protect the clients from potential harm or injury.

3. Research or Non-traditional Treatment Modalities. Approval for exceptional procedures, treatment modalities, etc., shall be approved in accordance with federal and state guidelines.

4. Operational Requirements. The facility shall:

- a. be fully operational for the business of providing substance abuse/addiction prevention/treatment during normal business hours and after hours as indicated/approved on original application or change notification approval;
- b. be available as a community resource, and maintain current schedule of area support groups;
- c. share space, telephones, or personnel with other entities only in compliance with R.S. 40: 2007.
- d. have active clients who are receiving services at the time of any survey after the initial survey;
- e. be able to accept referrals during hours of operation as specified on licensure application;
- f. utilize staff to provide services based on the needs of their current caseload of clients;
- g. have required staff on duty at all times during operational hours.

E. Required Facility Reporting. The facility director shall verbally/facsimile report these incidents to HSS within 24 hours of discovery. State-operated facilities are also required to follow OAD reporting policy:

1. fire and/or natural disasters;
2. any substantial disruption of program operation;
3. any death or serious injury of a client that may potentially be related to program activities; and
4. violations of laws, rules, and professional and ethical codes of conduct by facility personnel/volunteers.

F. Required Postings. The facility shall post a legible copy of the following documents in full view of clients, visitors, and employees:

1. the age appropriate Client Bill of Rights;
2. escape routes;
3. facility specific rules and responsibilities and grievance procedure;
4. current license and variances;
5. current activity schedule;
6. current survey findings.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1057.1 - 9, redesignated R.S. 40:1058.1 - 9.

HISTORICAL NOTE: Promulgated by 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 26:1457 (July 2000).

## **§7419. Personnel Requirements**

### **A. Standards of Conduct**

1. The facility, and all personnel in accordance within individual professional licensure, shall:

- a. protect the health, safety, rights, and welfare of clients;
- b. provide services designated on license;
- c. adhere to all applicable laws, regulations, policies, and procedures;
- d. maintain required licenses, permits and credentials; and
- e. adhere to professional and ethical codes of conduct.

2. Neither the facility nor any of its personnel shall:

- a. commit an illegal, unprofessional or unethical act;
- b. assist or knowingly allow another person to commit an illegal, unprofessional, or unethical act;
- c. knowingly provide false or misleading information;
- d. omit significant information from required reports and records or interfere with their preservation;
- e. retaliate against anyone who reports a violation or cooperates during a review, inspection, investigation, hearings or related activity; or
- f. interfere with Department reviews, inspections, investigations, hearings, or related activity. This includes taking action to discourage or prevent someone else from cooperating with the activity.

### **B. General**

1. Referrals. Facility personnel shall report violations of laws, rules, and professional and ethical codes of conduct to HSS and to appropriate licensing board when applicable. The facility shall maintain records and have written policies governing staff conduct and reporting procedures that comply with this §7419.

2. Staffing. A facility shall employ sufficient and qualified staff to meet the requirements and responsibilities required by licensure as well as the needs of each client being served.

3. Qualifying Experience. Any experience used to qualify for any position must be counted by using one year equals 12 months of full-time work. At no time will any professional staff be considered full time at two facilities.

4. Caseloads. All counselors (including full time, part time, and those who also have other duties) must have caseloads appropriate to available time, which shall be determined by the needs of the active clients and the level of treatment being provided.

5. Multiple Positions. A person may hold more than one position within the facility if that person is qualified to function in both capacities, and the required hours for each job are separate and apart for each position.

6. Credential Verification. Facility administration is responsible for assuring that all credentials are from accredited institutions, legal, and verified to deter the fraudulent use of credentials.

7. Clinical Services Director. A qualified professional supervisor or qualified professional counselor shall be designated, in writing, as responsible for supervising all treatment services and programs.

8. Contract Staff Services. Formal written agreements with professionals or other entities to provide services which may or may not be directly offered by facility staff are

required for contract services. Both parties shall review and document review of each agreement annually.

### **C. Training**

1. Orientation. Each employee shall complete at least eight hours of orientation prior to providing direct client care/contact. The content of the basic orientation provided to all employees at the time of employment with annual review shall include the following:

- a. policies/procedures and objectives of the facility;
- b. duties and responsibilities of the employee;
- c. organizational/reporting relationships;
- d. ethics and confidentiality;
- e. client's rights;
- f. standards of conduct required by the facility;
- g. information on the disease process and expected behaviors of clients;
- h. emergency procedures including disaster plan, evacuation;
- i. principals and practices of maintaining a clean, healthy and safe environment;
- j. additional information as appropriate to job duties, type of client, etc;
- k. universal precautions;
- l. violent behavior in the workplace;
- m. abuse/neglect;
- n. overview of Louisiana licensing standards;
- o. prevention overview, and
- p. basic emergency care of ill or injured clients until trained personnel can arrive.

2. In-Service. This educational offering shall assist the direct care/contact workers to provide current treatment modalities, and serve as refresher for subjects covered in orientation. Documentation of attendance for at least three hours per quarter is required. Additional educational programs are encouraged.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1057.1 - 9, redesignated R.S. 40:1058.1 - 9.

HISTORICAL NOTE: Promulgated by 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 26:1458 (July 2000).

## **§7421. Personnel Qualifications/Responsibilities**

### **A. Qualified Professional Supervisor (QPS) 1.**

#### **Qualifications**

a. The following professionals who are currently registered with their respective Louisiana board:

- i. licensed psychologist;
- ii. licensed clinical social worker;
- iii. licensed professional counselor.

b. The following professionals who are currently registered with their respective Louisiana boards and who can demonstrate two years of professional level counseling experience, and one year of professional level substance abuse counseling, or 90 clock hours (six semester hours) of substance abuse training post-certification, including the twelve core functions from an accredited college or university, or an educational provider approved by DHH may function as QPS. Documentation shall be available from the facility upon request. The professionals eligible to become QPS's are listed below:

- i. board certified substance abuse counselor (BCSAC);
- ii. licensed physician (MD);
- iii. registered nurse (RN);
- iv. board-certified compulsive gambling counselor (BCCGC);
- v. Masters-prepared social worker/counselor;
- vi. Masters-prepared counselor under the supervision of a licensed psychologist, licensed professional counselor (LPC), or licensed clinical social worker (LCSW).

2. Responsibilities. The QPS shall:

- a. provide direct client care utilizing the twelve core functions of the substance abuse counseling and/or specific functions related to professional license;
- b. serve as resource person for other professionals counseling substance abuse clients;
- c. attend and participate in care conferences, treatment planning activities, and discharge planning related to primary caseload and/or clients of professionals being supervised;
- d. provide on-site and direct professional supervision of treatment and any counselor-in-training, including but not limited to, activities such as individual/group counseling, or educational presentations;
- e. provide oversight and supervision of such activities as recreation, art/music, or vocational education, to assure compliance with accepted standards of practice;
- f. function as patient advocate in all treatment decisions affecting the client;
- g. be designated as the clinical services supervisor unless other QPSs are employed and available at the facility) and/or actively supervise QPC if program does not require full-time supervisor;
- h. assure that facility adheres to rules and regulations regarding all substance abuse treatment, e.g., group size, caseload, referrals, etc.;
- i. provide only those services which are appropriate to their profession.

B. Qualified Professional Counselor (QPC)

1. Qualifications. A QPC is a professional who is employed in the treatment of abuse/addiction disorders and who is currently licensed/certified by the appropriate Louisiana board as one of the following professionals:

- a. board certified substance abuse counselor (BCSAC);
- b. Licensed clinical social worker (LCSW);
- c. licensed professional counselor (LPC);
- d. licensed psychologist;
- e. licensed physician (MD);
- f. registered nurse (RN);
- g. board-certified compulsive gambling counselor (BCCGC);
- h. Masters-prepared social worker/counselor ;
- i. Masters-prepared counselor under the supervision of a licensed psychologist, licensed professional counselor (LPC), or licensed clinical social worker (LCSW).

2. Responsibilities. The QPC shall:

- a. provide direct care to clients utilizing the 12 core functions of substance abuse counseling and may serve as primary counselor to specified caseload;
- b. serve as resource person for other professionals and paraprofessionals in their specific area of expertise;
- c. attend and participate in client care conferences, treatment planning activities, and discharge planning;

- d. provide on-site and direct professional supervision of any paraprofessional or inexperienced professional;
- e. function as the patient advocate in all treatment decisions affecting the client;
- f. prepare and write notes/other documents related to client recovery, e.g. assessment, progress notes, treatment plans, etc.; and
- g. provide only those services that are appropriate to their profession.

C. Board Certified Prevention Specialist (BCPS)

1. Qualifications. Prevention Specialists shall be certified in accordance with requirements promulgated by the LSBCSAC.

2. Responsibilities. Duties include:

- a. program coordination;
- b. education and training;
- c. community organization;
- d. public policy;
- e. planning and evaluation; and
- f. professional responsibility.

D. Counselor in Training (CIT)

1. Qualifications:

- a. registered with the professional licensing board and in good standing at all times;
- b. actively pursuing certification at all times; and
- c. designated in writing as CIT by the facility and performing according to a written training plan under the auspices of the facility.

2. Responsibilities. The CIT shall:

- a. provide direct client care utilizing the core functions of substance abuse counseling only under the on-site supervision of facility employed QPS/QPC.
- b. not identify nor represent himself/herself as counselor.
- c. not perform any duties of counselor independently, without on-site supervision of facility employed QPS/QPC.
- d. never identify themselves as a consultant to any substance abuse facility.

3. Exceptions: CITs who have documented evidence of at least 40 hours of training (including orientation and the 12 core functions of substance abuse counseling) and 120 hours of direct supervision by QPS/QPC may perform counseling functions when the QPS/QPC is on duty or on-call and available for immediate assistance if needed.

E. Personnel in Training—Includes all students, persons working toward professional level licensing or certification in any profession listed in §7421 B., C., D., or F.

1. Qualifications:

- a. current registration with appropriate LA Board when required, and in good standing at all times;
- b. actively pursuing professional level preparations at all times; and
- c. designated in writing by facility, and performing in accordance with a written training plan under the auspices of the facility.

2. Responsibilities. Duties include:

- a. providing direct client care utilizing the standards developed by the professional board, and only under the direct supervision of the appropriate QPC or QPS;
- b. providing only those services in which the student has been properly trained and deemed competent to perform by the supervising QPC or QPS.

F. Support Professional Staff. Support professional staff includes employees, consultants, contract employees, or volunteers who provide services in the capacity of their profession, including but not limited to, pharmacists, dietitians, physicians, nurses, social workers, teachers, counselors, or psychologists.

1. Qualifications:

a. currently unencumbered license/registration with appropriate Louisiana Board (may be approved specifically by licensing Board, if encumbered), and

b. a professional as recognized by the certifying entity, rather than assistant, aide, technician, associate, etc.

2. Responsibilities. Duties include:

a. those within their respective board's delineated scope of practice only.

b. in-service, staff training, consultation to paraprofessionals and professionals and direct supervision, as needed to improve the overall quality of care being provided.

G. Volunteer

1. Qualifications. Volunteers must be:

a. appropriately screened and supervised to protect clients and staff;

b. oriented to facility, job duties, other pertinent information;

c. appropriately trained to meet requirements of duties assigned;

d. given a job description or written agreement; and

e. identified as volunteers.

2. Responsibilities. Duties include:

a. direct care activities only when qualified facility personnel present;

b. errands, recreational activities;

c. individual assistance to support services; and

d. other appropriately assigned duties.

H. Medical Director. Every facility licensed shall have a designated medical director. Primary prevention programs are not required to designate a medical director.

1. Qualifications. The medical director shall have a current, valid license to practice medicine in Louisiana.

2. Responsibilities. Medical director shall:

a. provide services required by facility to meet the Standards.

b. provide oversight for facility policy/procedure and staff regarding the medical needs of the clients being served in accordance with the current standards of medical practice; and

c. retain ultimate responsibility for directing the specific course of medical treatment for all clients.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1057.1 - 9, redesignated R.S. 40:1058.1 - 9.

HISTORICAL NOTE: Promulgated by 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 26:1459 (July 2000).

**§7423. Health and Safety**

A. Infection Control

1. Facility shall protect staff, clients, and visitors from the potential/actual harm of infectious disease by the following policies and procedures:

a. Universal Precautions. Education, practice, and implementation shall be applied.

b. Infection control program to report, evaluate, and maintain documentation pertaining to the spread of infectious disease, including data collection and analysis, corrective actions, and assignment of responsibility to designated medical staff person.

c. Strict adherence to all sanitation requirements.

2. Facility shall establish and maintain a clean and neat environment by the implementation of the following housekeeping policies and procedures:

a. Supplies/equipment shall be available to staff/clients.

b. Consistent and constant monitoring and cleaning of all areas of the facility shall be practiced.

c. Facility may contract for services necessary to maintain a clean and neat environment.

d. Directions shall be posted for sanitizing both kitchen and bathroom areas.

3. Domestic animals shall be:

a. properly vaccinated; and

b. managed in a way consistent with the goals of the program and the needs of the client, including those with allergies.

B. Sanitation

1. Food and waste shall be stored, handled, and removed in a way that will not spread disease, cause odor, or provide a breeding place for pests.

2. If there is evidence of pests, the facility shall contract for pest control.

3. Poisonous, toxic and flammable materials shall be labeled, stored, and used safely.

C. Safety

1. Environmental

a. The entire facility, including grounds, buildings, furniture, appliances, and equipment, shall be structurally sound, in good repair, clean, and free from health and safety hazards.

b. The facility shall comply with Americans with Disabilities Act (ADA).

c. The environment shall enhance client dignity and confidentiality.

d. The facility shall have adequate space, furniture, and supplies for the services described in the program description, including:

i. an adequate number of accessible drinking units;

ii. an adequate number of sanitized non-disposable or disposable hot/cold cups;

iii. clean, comfortable and appropriately furnished areas for various activities.

e. The facility shall have private counseling space. Staff shall have office space that is not required for other simultaneous activities.

f. The facility shall prohibit weapons of any kind on-site.

2. Evacuation/First Aid. The facility shall respond effectively during a fire or other emergency. Every program shall:

a. have emergency evacuation procedures that include provisions for the handicapped;

b. hold fire drills on each shift at least quarterly and correct identified problems promptly;

- c. be able to clear the building safely and in a timely manner at all times;
- d. post exit diagrams conspicuously throughout the program site;
- e. post emergency numbers by all phones; and
- f. have adequate first aid supplies that are visible and easy to access at all times.

3. Facility shall take all precautions possible to protect the staff, clients and visitors from accidents of any nature.

4. Facility shall have a written facility specific disaster plan, and staff shall be familiar with the contents of the plan as well as the location.

D. Emergency Care. Outpatient, Prevention and Education Programs may be exempt from these requirements if access to Emergency Medical Services is less than ten minutes.

1. At least one employee on site at each facility shall be certified in cardiopulmonary resuscitation and airway obstruction treatment and have training in dealing with out-of-hospital accidents and medical emergencies until emergency medical personnel and equipment can arrive at facility.

2. Facilities that have licensed nurses/physicians on duty during all hours of operation are exempt from this requirement.

#### E. Physical Plant Requirements

##### 1. Required Inspections

a. The facility shall pass all required inspections and keep a current file of reports and other documentation needed to demonstrate compliance with applicable laws and regulations. The inspections must be signed, dated, and free of any outstanding corrective actions. The following inspections are required:

- i. annual fire marshal inspection;
- ii. annual inspection of the alarm system by a licensed contractor;
- iii. quarterly fire alarm system test by facility staff;
- iv. annual kitchen inspection by Office of Public Health;
- v. gas pipe pressure test once every three years by the local gas company or a licensed plumber;
- vi. annual inspection and maintenance of fire extinguishers by personnel licensed or certified to perform those duties; and
- vii. regular inspections of elevators.

b. The following documentation shall be on file in facility:

- i. certificate of occupancy as required by local authorities;
- ii. DHH approval of the water supply/system;
- iii. DHH approval of the sewage system; and
- iv. documentation that the liquefied petroleum supply has been inspected and approved.

##### 2. Fire Notification/Protection Systems

a. A fire detection, alarm, and communication system required for life safety shall be installed, tested, and maintained in accordance with the facility's occupancy and capacity classifications.

b. Fire alarm systems shall be installed by agents registered with Office of State Fire Marshal.

c. Alarms shall be loud enough to be heard above normal noise levels.

d. Fire extinguishers shall be mounted throughout the facility as required by code and approved by Office of State Fire Marshal.

i. Each laundry and walk-in mechanical room shall have at least one portable A:B:C extinguisher, and each kitchen shall have at least one B:C fire extinguisher.

ii. Each fire extinguisher shall have the required maintenance service tag attached.

e. Staff shall conduct quarterly inspections of fire extinguishers for proper location, obvious physical damage, and a full charge on the gauge.

##### 3. Exterior Space Requirements. A provider shall:

a. ensure that all structures on the grounds of the facility that are accessible to clients are maintained in good repair and are free from an excessive hazard to health or safety;

b. maintain the grounds of the facility in an acceptable manner and ensure that the grounds are free from any hazard to health or safety;

c. store garbage and rubbish securely in non-combustible, covered containers that are emptied on a regular basis;

d. separate trash collection receptacles and incinerators from client activity areas and locate all containers so as to avoid being a nuisance to neighbors;

e. keep fences in good repair;

f. fence off or have natural barriers around areas determined to be unsafe, including steep grades, cliffs, open pits, swimming pools, high voltage boosters, or high speed roads.

##### 4. Interior Space Requirements

a. Group Rooms. Seating for each client shall be provided with appropriate furnishings.

b. Leisure/Craft Areas. Materials appropriate to the clients being treated at the facility shall be stocked.

c. Bathrooms. Minimum facilities include:

i. adequate operational fixtures to meet Louisiana State Plumbing Code. All fixtures must be functional and have the appropriate drain and drain trap to prevent sewage gas escape back into the facility;

ii. an adequate supply of hot water for the number of clients and the program schedule. Hot water temperature at point of service to client shall be between 105 and 120 degrees Fahrenheit;

iii. toilets shall have seats and be located to allow access without disturbing other clients during sleeping hours and/or treatment sessions;

iv. adequate supply of toilet paper, towels, and soap;

v. doors to allow for individual privacy;

vi. external emergency release mechanism;

vii. safe and adequate supply of cold running water;

viii. safety mirrors attached to the walls at convenient heights and other furnishings necessary to meet the clients' basic hygiene needs;

ix. functional toilets, wash basins, and other plumbing or sanitary facilities which shall be maintained in good operating condition, and shall be kept free of any materials that might clog or otherwise impair their operation.

d. Administrative and Counseling Space i.

Administrative office(s) for records, secretarial work and bookkeeping shall be separate and secure from client areas.

ii. Space shall be designated to allow for private discussions and counseling sessions.

e. Doors and Windows. Outside doors, windows and other features of the structure necessary for safety and comfort of clients shall be secured for safety within 24 hours after they are found to be in a state of disrepair. Total repair should be effected as soon as possible.

i. A provider must have insect screening for all opened windows. This screening shall be readily removable in emergencies and shall be in good repair.

ii. All doors can be readily opened from both sides.

iii. All windows open to an outside view or a patio/porch area and are available for use as an alternate means of escape, if needed.

f. Storage. A provider shall:

i. ensure that there are sufficient and appropriate storage facilities;

ii. secure all potentially harmful materials.

#### 5. Exits

a. Exit doors and routes shall be lighted and unobstructed at all times.

b. There shall be an illuminated "exit" sign over each exit. Where the exit is not visible, there shall be an illuminated "exit" sign with an arrow pointing the way.

c. Rooms for 50 or more people have exit doors that swing out.

d. No door may require a key for emergency exit. Locked facilities shall have emergency exit door releases as described in the Life Safety Code and/or approved by the Office of State Fire Marshal.

e. Windows shall provide a secondary means of escape.

f. Every building shall have at least two exits that are well separated.

g. Every multiple-story building shall have at least two fire escapes (not ladders) on each story that are well separated. Fire escapes shall:

i. be made of non-combustible material;

ii. have sturdy handrails or walls on both sides; and

iii. provide a safe route to the ground.

h. Stairs and ramps shall be permanent and have non-slip surfaces.

i. Exit routes higher than 30 inches (such as stairs, ramps, balconies, landings, and porches) shall have full-length side guards.

6. Electrical Systems. All electrical equipment, wiring, switches, sockets and outlets are maintained in good order and safe condition. Any room, corridor, stairway and exit within a facility is sufficiently illuminated.

a. The facility shall have adequate lighting to provide a safe environment and meet user needs.

b. Lighting shall be provided outside the building and in parking lots.

c. Light bulbs shall have shades, wire guards or other shields.

d. Emergency lighting shall illuminate "exit" routes.

#### 7. Ventilation

a. The facility shall not use open flame heating equipment or floor furnaces, unvented space heaters, or portable heating units.

b. Occupied parts of the building, including kitchen and laundry areas, shall be air conditioned and temperature

should remain between 65 degrees and 85 degrees Fahrenheit.

c. The entire facility shall be adequately ventilated with fresh air. Windows used for ventilation shall be screened.

d. Provider shall take all reasonable precautions to ensure that heating elements, including exposed hot water pipes, are insulated and installed in a manner that ensures the safety of clients and staff.

#### 8. Plumbing

a. Safe, clean, cold drinking water shall be readily available to all clients.

b. The plumbing systems shall be designed, installed, operated and maintained in a manner that is designed to provide an adequate and safe supply of water for all required facility operations and to facilitate the complete and safe removal of all storm water and waste water.

#### 9. Finishes and Surfaces

a. Lead-based paint or materials containing asbestos shall not be used.

b. Floor coverings must promote cleanliness, must not present unusual problems for the handicapped and have flame-spread and smoke development ratings appropriate to the use area (e.g. client's room versus exit corridor).

c. All variances in floors shall be easily identified by markings, etc. to prevent falls.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1057.1 - 9, redesignated R.S. 40:1058.1 - 9.

HISTORICAL NOTE: Promulgated by 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 26:1461 (July 2000).

### **§7425. Rights, Abuse, Exploitation, and Neglect**

A. Client's Rights. Involuntary hospitalization/commitment does not mean loss of your rights to make decisions about one's life. The client shall have the right to expect the following inclusive but not exclusive rights:

1. assistance with healing of family relationships;

2. protection from unsafe and/or unskilled care by any person associated with the facility;

3. protection from unqualified persons providing services under the auspices of treatment;

4. consideration and respect toward the client, family and visitors when those people treat the facility staff with respect and consideration;

5. protection of personal property approved by the facility; and

6. protection from retaliation when client exercises his or her rights.

B. Adult Bill of Rights. Adults have the right to:

1. a humane environment that provides reasonable protection from harm and appropriate privacy for personal needs;

2. be free from abuse, neglect, and exploitation;

3. be treated with dignity and respect;

4. appropriate treatment in the least restrictive setting available that meets individual needs;

5. be told about the program's rules and regulations before admission;

6. be told before admission:

- a. the condition to be treated;
  - b. the proposed treatment;
  - c. the risks, benefits, and side effects of all proposed treatment and medication;
  - d. the probable health and mental health consequences of refusing treatment; and
  - e. other available treatments which may be appropriate;
7. accept or refuse treatment after receiving the explanation in paragraph 6 above;
8. change of mind at any time (unless specifically restricted by law);
9. a treatment plan designed to meet individual treatment needs, and the right to take part in developing that plan;
10. meet with staff to review and update the treatment plan on a regular basis;
11. refuse to take part in research without affecting regular care;
12. refuse unnecessary and/or excessive medication;
13. not to be restrained or placed in a locked room by self unless a danger to self or others;
14. have personal information kept confidential and to be told about the times when the information can be released without your permission;
15. communicate with people outside the facility. This includes the right to have visitors, to make telephone calls, and to send and receive sealed mail. This right may be restricted on an individual basis by ones doctor or the professional in charge of the program if it is necessary for treatment or for security, but even then the client may contact an attorney or DHH at any reasonable time;
16. be informed in advance of all estimated charges and any limitations on the length of services;
17. receive an explanation of treatment or rights while in treatment;
18. leave the facility within four hours of requesting release (if individual consented to treatment), unless a physician determines that he or she poses a threat of harm to self and others;.
19. make a complaint and receive a fair response within a reasonable amount of time;
20. complain directly to DHH at any reasonable time;
21. get a copy of these rights before admission, including the address and phone number of DHH;
22. have rights explained in simple terms, in a way that can be understood, within 24 hours of being admitted.

#### C. Abuse, Neglect, and Exploitation

1. Reporting. All allegations of client abuse, neglect, and exploitation shall be reported verbally/facsimile within 24 hours, and confirmed in writing to HSS within seven days.
2. Abuse. Client abuse includes:
  - a. any sexual activity between facility personnel and a client;
  - b. corporal punishment;
  - c. nutritional or sleep deprivation;
  - d. efforts to cause fear;
  - e. the use of any form of communication to threaten, curse, shame, or degrade a client;
  - f. restraint that does not conform with these rules;
  - g. coercive or restrictive actions that are illegal or not justified by the client's condition taken in response to

the client's request for discharge or refusal of medication or treatment; and

h. any other act or omission classified as abuse by Louisiana law.

#### 3. Neglect. Neglect examples include:

- a. failure to provide adequate nutrition, clothing, or health care;
- b. failure to provide a safe environment free from abuse or danger;
- c. failure to maintain adequate numbers of appropriately trained staff;
- d. any other act or omission classified as neglect by Louisiana law.

#### 4. Exploitation. Examples of exploitation include:

- a. use of a client's personal resources, such as credit card, medical assistance card, or insurance card, to bill for inappropriate service;
- b. use of the client's food stamps or other income to purchase food/services used primarily by others;
- c. using the client to solicit money or anything of value from the public, or others.

5. Sexual Exploitation. It may include sexual contact, a request for sexual contact, or a representation that sexual contact or exploitation is consistent with or part of treatment.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1057.1 - 9, redesignated R.S. 40:1058.1 - 9.

HISTORICAL NOTE: Promulgated by 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 26:1463 (July 2000).

### Subchapter C. Children/Adolescent Programs and Primary Prevention

#### §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.

1. The program lectures, and written materials shall be age-appropriate and easily understood by clients.

2. The program shall involve the adolescent's family or an alternate support system in the process or document why this is not appropriate.

3. Staff shall not provide, distribute, or facilitate access to tobacco products.

a. Staff shall not use tobacco products in the presence of adolescent clients.

b. The staff shall prohibit adolescent clients from using tobacco products on the program site or during structured program activities.

B. Staffing. The following staffing requirements are minimum standards and do not restrict the facility from utilizing additional employees.

1. Any facility employee who provides direct care to children/adolescents shall meet the requirements of the *Louisiana Children's Code Article 116*. Specifically, the employee may have no documented history indicating the

possibility that he/she would endanger the child. Facility shall make every effort to determine criminal history of employees.

2. The facility shall ensure that only qualified professional staff (R.S. 40:1098.2) plan, supervise, or provide education or counseling or training in the emotional, mental health, and substance abuse problems to adolescents.

3. All direct care employees shall have training in human adolescent development, family systems, adolescent psycho-pathology and mental health, substance abuse in adolescents, and adolescent socialization issues.

4. All direct care employees and volunteers shall be trained and competent to use personal and physical restraint.

#### C. Special Considerations

1. Facilities shall address the special needs of adolescents and protect their rights.

2. Adults and adolescents may be mixed for specific groups or activities when no conflict exists.

3. The facility shall obtain consent for admission and authorization to obtain medical treatment from parent or guardian prior to the time of admission for all clients under the age of majority.

4. If functional status of client is not age appropriate, facility shall provide additional supervision to provide for safety of all clients.

D. Minor's Bill of Rights. In accordance with the *Louisiana Children's Code, Article 116*; the minor has the right to:

1. an attorney and the right to communicate with that attorney in a private place at all times;

2. a copy of client rights in a language that can be reasonably understood;

3. receive and send letters, to receive and make telephone calls, to receive visitors (at least weekly);

4. spend a reasonable amount of money on small items, such as snacks, and soft drinks;

5. wear one's own clothes and keep personal things;

6. have a private space for personal belongings;

7. be disciplined in a way that is appropriate. Restraint and seclusion cannot be used to punish or discipline;

8. medicine that makes one feel better. If the medicine makes the minor feel bad, the individual should tell the nurse, doctor or client advocate;

9. treatment in a place that allows the most freedom possible;

10. treatment plan that is set up to meet individual needs;

11. leave the facility when condition improves enough so that treatment can be received in a less restrictive setting;

12. have a private doctor examine client at his or her own expense.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1057.1 - 9, redesignated 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 26:1464 (July 2000), LR 31:670 (March 2005).

## Subchapter D. Core Requirements for Treatment Programs

### §7431. Treatment/Detoxification Programs

A. General. If treating adolescents and/or children, follow §7427 in addition to other requirements.

B. Professional Staffing Standards. The following are the minimum staffing requirements for all treatment/detoxification programs and do not restrict any facility from utilizing additional staff. Specific programs may have additional staffing requirements.

1. Physician. Every licensed treatment or detoxification program shall have a designated medical director, who provides medical oversight of all care provided, participates in the development of policies and procedures of the facility, and provides medical care if needed. The following duties may be performed by a qualified advance practice registered nurse when in collaborative practice with the medical director. Additional duties include, non-exclusively:

a. writing the admission/discharge orders, when required;

b. writing/approving all prescription medication orders;

c. writing and providing education regarding the protocols for administering all medications on-site, including non-prescription medications;

d. supervising or providing services and care; and

e. providing consultative and on-call coverage to assure health and safety of clients in the facility.

2. Nursing. Each facility shall have adequate nurses to provide nursing services when indicated by the diagnosis, nursing needs of the clients admitted to the facility, administration of medicines and/or treatments, and general physical health of clients. Adequate shall be defined as having nursing staff available whenever a client has needs requiring professional nursing skills.

3. Pharmacist. Any facility that dispenses/administers prescription medication on-site shall employ adequate staff to assure that any prescription medication administered and/or dispensed on-site shall meet the requirements of R.S. 37:1161 et seq. Facility shall have written agreement with a licensed pharmacist or licensed physician to provide on-site service and consultation and evaluation of medication policy and procedure of facility to dispense prescriptions, reconcile (administration and dispensing ) inventories at least every 30 days, and to maintain medication records for at least three years.

4. Qualified Professional Supervisor (QPS). Every facility shall have QPS on-duty during operational hours at least one hour per week per counselor, two hours per week per counselor-in-training, and additionally as indicated by the needs of the active clients. Primary duties include supervising QPCs and CITs during counseling sessions, treatment planning and counseling for clients who have complex needs/diagnoses. Specific additional requirements for 24-hour facilities are listed in the applicable section.

5. Qualified Professional Counselor (QPC). Each outpatient program shall have full-time QPC on duty during all hours of operation, and as determined by needs of the active clients, on-call after normal business hours. Specific requirements for 24-hour facilities are listed in the applicable section.



C. Treatment/Detoxification Protocols. All services shall be delivered according to a written plan and a posted activity schedule. The treatment program shall:

1. be age and culturally appropriate for the population served;
2. demonstrate effective communication and coordination;
3. provide for appropriate utilization of services;
4. be an environment that enhances the positive self-image of clients and preserves their human dignity;
5. administer/dispense medication safely and legally, only when prescribed or approved by the staff medical doctor or advanced practice registered nurse (APRN);
6. require professional participation in all required components of the treatment program;
7. assure that the hours of scheduled treatment activity meet requirements of the program license; and
8. utilize the 12 core functions of substance abuse counseling and other current standards of practice.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1057.1 - 9, redesignated R.S. 40:1058.1 - 9.

HISTORICAL NOTE: Promulgated by 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 26:1466 (July 2000).

#### **§7433. Admission, Discharge, or Transfer**

A. Admission Requirements. Initial Assessment and Diagnosis of specific abuse/addictive disorder/disease by the medical director or other licensed qualified professional (physician, advanced practice registered nurse-certified in mental health, licensed social worker, licensed professional counselor or licensed psychologist) as currently defined in the Diagnostic and Statistical Manual for Mental Disorders (DSM).

1. Initial Admission Diagnosis. Process shall contain:
  - a. physical examination within 72 hours when one is indicated by the M.D./nursing assessment/screening process.
  - b. laboratory examinations as required to prevent spread of contagious/communicable disease, and as indicated by physical examination or nursing assessment, including drug screening when history is inconclusive or unreliable.
  - c. medical/nursing assessment/history and screening interview.
  - d. psycho-social evaluation□QPC/QPS shall document a psycho-social history that provides a thorough understanding of the client's history and present status including:
    - i. circumstances leading to admission;
    - ii. alcohol and other drug use, past and present (including amount, frequency, route of administration, and time/date of last use);
    - iii. past psychiatric and chemical dependency treatment;
    - iv. significant medical history and current health status;
    - v. family and social history;
    - vi. current living situation;

- vii. relationships with family of origin, nuclear family, and significant others;
- viii. education and vocational training;
- ix. employment history (including military) and current status;
- x. legal history and current legal status;
- xi. emotional state and behavioral functioning, past and present; and
- xii. strengths, weaknesses, and needs.

e. intake screening to include: vocational, economic, educational, and criminal/arrest information; and  
f. appropriate assignment to treatment modality with referral to other appropriate services as indicated.

i. Clients shall have access to HIV counseling and testing services directly or through referral. Such counseling and testing shall be voluntary, anonymous/confidential, and not limited by ability to pay.

ii. The program shall make testing for tuberculosis and sexually transmitted diseases available to all clients unless the program has access to test results obtained during the past year. The services may be provided directly or through referral as long as appropriate follow-up referral/care is also provided.

2. Additional Requirements. Additional admission requirements are:

- a. availability of appropriate physical accommodations;
- b. legal authority or voluntary admission;
- c. availability of professionals to provide services needed as indicated by the initial assessment and diagnosis; and
- d. written documentation that client/family consents to treatment and understands the diagnosis and treatment modality.

3. Client/Family Orientation. Each facility shall provide orientation, confidentially and efficiently, primarily by qualified professional, concerning:

- a. visitation;
- b. family involvement;
- c. safety;
- d. authorization to provide treatment;
- e. potential problems;
- f. projected duration of treatment;
- g. consequences of non-compliance;
- h. treatment methodology; and
- i. all pertinent information, including fees and consequences of non-payment of fees.

4. Re-admissions. Each facility shall have written re-admission standards which address criteria, length of stay, authorization to make exceptions, and crisis intervention.

B. Discharge Criteria. Each program shall develop and follow appropriate written criteria to decide when/how clients will be discharged or transferred to another level.

1. Indicators. The criteria shall utilize indicators to determine:

- a. satisfactory completion of the level;
- b. need for referral or transfer to another level or facility; and
- c. when client should be discharged before completing the program.

2. Discharge Plan. A written, client-specific plan to provide reasonable protection of continuity of services, that shall include:

- a. client transfer or referral/assignment to outside resources, continuing care appointments, crisis intervention assistance, and discharge summary;
- b. documented attempts to involve family or an alternate support system in the discharge planning process;
- c. planning before the client's scheduled discharge;
- d. individual goals or activities to sustain recovery; and
- e. signature of the client or consenting person/guardian.

3. Discharge Summary. When client is being transferred to another level of treatment, two working days are allowed for completion. In other situations 30 days are allowed. The summary must be written, client specific, and include:

- a. needs and problems identified at the time of admission (may be attached);
- b. services provided;
- c. assessment of the client's progress towards goals;
- d. circumstances of discharge; and
- e. evidence that continuity of care recommended following discharge.

4. Request for Discharge. When such a request is received, the facility shall:

- a. not hold a voluntary client against the consentor/guardian's will;
- b. have written procedures for handling discharges and discharge requests that comply with applicable statutes;
- c. not try to keep a client in treatment by coercion, intimidation, or misrepresentation;
- d. not say or do anything to influence the client's decision that is not justified by the client's condition.

C. Transfer Process. Transfer procedures between two facilities to provide continuum of care which may be based on the compilation of client data rather than completing additional medical history/examination/physician orders, psycho-social assessment, treatment plan, and other pertinent information upon admission to inpatient or outpatient care.

1. Sender requirements:

- a. transfer all client information within two working days of transfer;
- b. notify the receiving facility (in writing) simultaneously with arrival of client any information that will be needed to care for client before transfer information arrives; and
- c. request and receive approval from receiving facility prior to transfer.

2. Receiver requirements:

- a. provide client with orientation to facility; and
- b. update all information received in transfer.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1057.1 - 9, redesignated R.S. 40:1058.1 - 9.

HISTORICAL NOTE: Promulgated by 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 26:1467 (July 2000).

## §7435. Client Records

A. Client Record Standards. The facility is required to maintain a clinical record according to current professional standards for each client.

1. Safeguards shall be in place to prevent unauthorized access, loss, and destruction.

2. Client record can be copied and/or transferred from one facility to another provided that client signs authorization for transfer of record and provided that confidentiality of information is strictly in adherence with 42 CFR, Part 2.

3. Client records shall be maintained at the facility where the client is currently active and for six months after discharge. Records may then be transferred to a centralized location for maintenance in accordance with standard practice and state and federal laws.

4. Confidentiality. Records shall be:

a. accessible only to authorized personnel trained in confidentiality and others granted access by legal authority such as surveyors, investigators, etc.;

b. not shared with any other entity unless approved in writing by client, except in medical emergencies; and

c. kept in compliance with 42 CFR, Part 2.

5. Record-keeping Responsibility. A trained medical records person or professional shall be designated as responsible for the client records.

B. Contents. Client record shall accurately document treatment provided and client response in accordance with professional standards of practice at all times. This record shall contain all pertinent past and current medical, psychological, social and other therapeutic information.

1. Minimum client record requirements for Treatment/Detoxification Programs.

a. Admission diagnosis and referral information;

b. Client information/ data - name, race, sex, birth date, address, telephone number, social security number, school/employer, and next of kin/emergency contact; Screening  See program specific requirements.

d. Medical limitations, such as major illnesses, allergies; and

e. Attendance, participation in services/activities.

2. Additional Minimum Requirements for Client Treatment Records Contents

a. Initial assessment and diagnosis. See §7431.C.1.

b. Treatment plan. The plan is a written list of the client's problems and needs based on admission information and updated as indicated by progress or lack of progress. Additionally, the plan shall:

i. contain input from primary counselor and client within 72 hours after admission, then information from other disciplines added as client is evaluated and treated;

ii. be reviewed and revised as required, or more frequently as indicated by client needs;

iii. contain client-specific, measurable goals that are clearly stated in behavioral terms;

iv. contain realistic and specific expected achievement dates;

v. contain how facility will provide strategies/activities to help the client achieve the goals;

vi. be followed consistently by all staff members; and

vii. contain complete, pertinent information related to the mental, physical, and social needs of the client; and

c. Diagnostic laboratory and other pertinent information, when indicated.

d. Progress Notes. In accordance with current professional standards of practice, progress notes shall:

i. document implementation of the treatment plan and results;

ii. document services provided to the client. This may be done by filing a copy of the program schedule in the client record and documenting the client's level of participation in the progress notes;

iii. be completed weekly by the QPS/QPC to document progress toward stated treatment plan goals unless client is seen on a less frequent basis in accordance with the treatment plan; and

iv. be verified and co-signed by QPS/QPC when prepared or written by CIT.

e. Client Contact Report. The staff member involved in the incident shall prepare and file a written report.

f. Other pertinent information related to individual client as appropriate.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1057.1 - 9, redesignated R.S. 40:1058.1 - 9.

HISTORICAL NOTE: Promulgated by 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 26:1467 (July 2000).

#### **§7437. Core Functions/Services**

A. Core Functions. Core functions are: Screening, Intake, Orientation, Assessment, Treatment Planning, Counseling, Case Management, Crisis Intervention, Client Education, Referral, Reports and Record Keeping, and Consultation with Professionals.

1. Assessment-core function in which a counselor/program identifies and evaluates an individual's strengths, weaknesses, problems, and needs for the development of the treatment plan. Collection of data from client and/or family/others sufficient to formulate an individualized and client-specific treatment plan or referral to appropriate level of care. Any assessment leading to a diagnosis shall be performed by a professional qualified to diagnose.

2. Case Management-core function in which services, agencies, resources, or people are brought together within a planned framework of action toward the achievement of established goals. It may involve liaison activities and collateral contracts with other providers/facilities.

3. Client Education-core function in which information is provided to individuals and groups concerning alcoholism and other drug abuse, positive lifestyle changes, and the available services and resources. Educational group size is not restricted and may be offered as outreach program. Program shall:

a. follow a course outline that identifies lecture topics, activity schedule, and major points to be discussed;

b. include benefits of participation in appropriate self-help groups; and

c. not identify the activity as a counseling session.

4. Client Orientation-core function in which the client is informed regarding:

a. general nature and goals of the program;

b. rules governing client conduct and infractions that can lead to disciplinary action or discharge from the program;

c. availability of services;

d. costs; and

e. client's rights.

5. Consultation with Professionals-core function in which functional relationship with counselors and other credentialed health care professionals is provided as required to assure comprehensive quality care for the client including, but not limited to, treatment of children, adolescents, or clients/family members who have complex problems or who are dually diagnosed with abuse/addiction disorder and mental illness.

6. Counseling (Individual/Group) Services□core function in which appropriate support is provided to the client by those professionals qualified to provide therapeutic services.

a. Special skills are used to assist individuals, families, or groups in achieving objectives through:

i. exploration of a problem and its ramifications;

ii. examination of attitudes and feelings;

iii. consideration of alternative solutions; and

iv. decision making and problem solving.

b. Counseling Session (individual, group, or family) is a documented interaction between qualified professional personnel and client or client and significant others.

c. All counseling groups shall be homogenous and no more than 12 clients.

d. Counseling sessions shall last at least 30 minutes.

7. Crisis Intervention Services□core function in which appropriate assistance during emergencies including 24-hour telephone coverage by qualified counselor to provide telephone assistance to prevent relapse, to provide referral to other services, and to provide support during related crises. Facilities may have written contract with another facility to provide coverage only if the caller is automatically transferred or given directions to reach professional assistance, or receive a call from a professional within a 30-minute time frame.

8. Intake-core function in which information is gathered about a prospective client. Information is given to a prospective client about the treatment facility and facility's treatment and services.

9. Referral-core function in which appropriate services not provided by facility are identified, and client/family is assisted to optimally utilize the available support systems and community resources. Facility shall provide appropriate resource information regarding local agencies to client/family upon need/request and/or procedures to access, including but not limited to, vocational services, community services, and organizations to support recovery such as transitional living services, transportation, and vocational services. Additionally, facility will be expected to:

a. provide access to appropriate health care and mental health services;

b. refer pregnant clients who are not receiving prenatal care to an appropriate health care provider and monitor follow-through; and

c. refer clients to ancillary services necessary to meet treatment goals.

10. Reports and Record Keeping-core functions in which results of the assessment and treatment planning are recorded. Written reports, progress notes, client data, and discharge summaries and other client related documentation is recorded in the client record. See §7435.

11. Screening-core function that is the determination of whether a client meets the program's admission criteria. It uses information such as the person's reason for admission, medical and substance abuse history, and other needed information to determine client's need for treatment, and/or appropriateness of admission.

12. Treatment Planning-core function in which the counselor and the client:

- a. identify and rank problems needing resolution;
- b. establish agreed upon immediate objectives and long-term goals; and
- c. decide on a treatment process, frequency, and the resources to be utilized. Documentation of treatment planning process shall be in accordance with current standards of practice.

#### B. Services

##### 1. Toxicology Services

a. Programs are required to have on-site or written agreement for toxicology services with a laboratory with appropriate Clinical Laboratories Improvement Amendments (CLIA) certification for testing.

b. If collection is performed on-site, facility shall have written protocols for collection of specimens in accordance with current standards of practice and have written approval by the testing laboratory.

c. The minimal set of substances required to be screened for toxicology are subject to annual approval by OAD.

2. Contract Services. Programs may use an outside source to provide any of the services listed above, however, the facility retains responsibility for the service.

3. Formal written agreements with professionals or other entities to provide services which may or may not be directly offered by facility staff:

- a. are required for contract services;
- b. both parties shall review and document review of each agreement annually;
- c. the facility retains full responsibility for all services provided by contract, unless client is discharged from original facility and admitted to contract facility;
- d. all services provided by contract shall meet the requirements of these standards and be provided only by qualified providers (licensed if required).

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1057.1 - 9, redesignated R.S. 40:1058.1 - 9.

HISTORICAL NOTE: Promulgated by 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 26:1469 (July 2000).

#### Subchapter E. Outpatient Programs

##### §7439. Outpatient Counseling Programs

A. Purpose. Programs provide non-residential treatment services for clients who require on-going support on a regular or irregular basis, such as:

1. Continuing Care for those who have completed primary treatment and require minimal support to avoid relapse;

2. Early Intervention for those who have been identified as substance abusers and referred for education, activities, or support services designed to prevent progression of disease;

3. Initial point of entry/reentry. Activities related to assessment, evaluation, diagnosis and assignment of level of care are provided, including transfer between facilities and/or treatment modalities, relapse assessment, and assignment to level of care;

4. Combination of the above

Note: Facility license is not required for individual or group practice of licensed counselors/therapists providing the above services under the auspices of their individual license(s).

B. Staffing. All requirements are in addition to §7431.

1. QPS-on-call as needed for crisis intervention.

2. QPC-hours of operation, and on-call as needed for crisis intervention.

3. Nursing and Pharmacy  not required, unless designated on license.

4. Caseload size is based on needs of the active clients to ensure effective, individualized treatment and rehabilitation. Approval by OAD or HSS is required in writing when caseload exceeds 50 active clients. For this standard, *active* is defined as being treated at least every 90 days.

C. Client Functional Status. Clients must be able to function independently in outpatient setting with appropriate support.

D. Special Considerations. When these services are court ordered, facility will provide all services in accordance with these licensing standards, maintain court related information, and initiate necessary communications to facilitate the court referral process.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1057.1 - 9, redesignated R.S. 40:1058.1 - 9.

HISTORICAL NOTE: Promulgated by 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 26:1470 (July 2000).

##### §7441. Intensive Outpatient Treatment Programs

###### A. General

1. All requirements are in addition to core requirements. Any physical examination conducted by a physician pursuant to §7433.A.1.a may be conducted by telemedicine utilizing video conferencing technology provided that a licensed health care professional shall be in the examination room with the patient at the time of the video conference.

2. Outpatient treatment facilities offer increased levels of responsibility for clients to apply knowledge and to practice skills in structured and non-structured settings.

3. Organized and structured day/evening treatment sessions are offered for at least nine hours per week on three or more days per week.

B. Staffing. All requirements are in addition to §7431 unless otherwise noted .

1. Supervisor (QPS). Ten hours weekly during hours of operation.

2. Counselor (QPC). Counselor shall be on site during all hours of operation and available for crisis intervention as needed.

3. Caseload. Counselor shall have no more than 25 active clients unless written approval is granted by OAD or HSS. For this standard, *active* is defined as being treated at least every 30 days.

4. Groups (counseling) shall not exceed 12 clients, but may be smaller in keeping with the needs of the clients.

5. Facility may use outpatient counseling standards for those clients who do not receive intensive outpatient treatment, however, the client must meet criteria for functional status for outpatient counseling and be designated as counseling client.

C. Client Functional Status. Clients shall be able to function with limited supervision within their existing environment or in environments designed to provide support, but cannot independently maintain stability for at least 72 hours.

D. Special Considerations. Treatment plan review/adjustments shall be documented in progress notes weekly by counselor, and by other disciplines as needed to assure continuity of care.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1057.1 - 9, redesignated R.S. 40:1058.1 - 9.

HISTORICAL NOTE: Promulgated by 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 26:1471 (July 2000), amended by HCR No. 70 of the 2008 Regular Legislative Session.

#### **§7443. Opiate Addiction Treatment Programs**

A. General. All requirements are in addition to core requirements.

1. Opiate addiction treatment programs detoxify chronic opiate addicts from opiates and opiate derivatives and maintain the chronic opiate addict utilizing a synthetic narcotic until the client can achieve recovery through a spectrum of counseling and other supportive/rehabilitative services.

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. Treatment Phases/Specific Requirements

1. Initial Treatment. Intensive assessment and intervention phase lasting from three to seven days in duration. Services to be provided are:

- a. admission verification by physician that treatment is medically necessary as determined by physical examination and medical diagnosis ( prior to administering of any medication).
- 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. individual counseling comprised of at least four individual counseling sessions during this phase;
- c. development of a treatment plan within 30 days with input by all disciplines, client and significant others; and
- d. random monthly drugs of abuse/alcohol screens.

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. continuous evaluation by the nurse of the client's use of medication/treatment from other sources;
- c. documented reviews of the treatment plan every 90 days in the first two years of treatment by the treatment team; and
- d. progress notes addressing response to treatment at least every 30 days.

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. counseling of the type and quantity determined by the indicators and the reason for the medically supervised withdrawal from the synthetic narcotic; and

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

C. Counseling. Type and quantity shall be based on the assessment and recommendations of the treatment team and shall meet the following requirements:

1. Written documentation shall support decisions of the treatment team including indicators such as positive drug screens, maladjustment to new situations, inappropriate behavior, criminal activity, and detoxification procedure.

2. All counseling shall be provided individually or in small (not to exceed 12 clients) homogenous groups provided that group counselor is familiar with all clients and documents all contacts in the client record.

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

4. Counseling shall be provided when requested by client/family.

D. Staffing. All requirements are in addition to §7431.

1. Pharmacist. Licensed pharmacist or licensed dispensing physician, in accordance with R.S. 38:1161 et seq., shall:

a. dispense all medications;

b. reconcile administration and dispensing inventory records at least every 30 days; and

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. QPS. On-site five hours per week per 100 clients.

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.

5. Physician. Sufficient hours on-duty and on-call as needed during hours of operation.

E. Client Admission Criteria

1. Facility shall verify that the client:

a. is at least 18 years old, unless the client has parental consent, and

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. regularity of clinic attendance;

c. absence of serious behavioral problems;

d. absence of known drug related criminal activity during treatment;

e. stability of home environment and social relationships;

f. assurance that take home medication can be safely stored;

g. whether the benefit to the patient outweighs the risk of diversion.

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.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1057.1 - 9, redesignated 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 26:1471 (July 2000), LR 31:671 (March 2005).

#### **Subchapter F. Twenty-four Hour Facilities**

#### **§7445. Additional Core Requirements for twenty-four hour facilities**

##### **A. Physical Plant Requirements**

1. Kitchens. Kitchens used for meal preparations by either staff or clients shall be appropriately sized and provided with the necessary equipment for the preparation, storage, serving and clean-up of all meals provided to the

clients/staff. In addition, if clients prepare meals, additional equipment and space will be required. All equipment shall be maintained in working order.

a. Trash containers shall be made of metal or United Laboratories-approved plastic.

b. Trash containers in kitchens and dining area shall be covered.

2. Staff Quarters. Live-in staff shall have adequate, separate living space with a private bathroom (toilet, wash basin, and tub/shower).

3. Leisure. Allotted leisure space shall be adequate for the capacity designated on the license and approved by DHH-Engineering and Planning. Each living unit of any residential facility shall contain a space for the free and informal use of clients. This space shall be constructed and equipped to meet programmatic goals.

4. Dining Area. Space shall be provided that permits clients, staff and guests to eat together in small groups and is clean, well-lighted, ventilated and attractively furnished.

5. Bedrooms. Mobile homes shall not be used for client sleeping areas. No more than four clients may occupy a designated bedroom space unless the floor plan is approved by DHH sections of Engineering and Professional Review, Fire Marshal, OAD and HSS. Sleeping areas shall have at least:

a. 80 usable square feet per person in single-occupancy rooms;

b. 60 usable square feet per person in multiple-occupancy rooms (or 50 square feet per person if bunk beds are used). Bunk beds shall not be used for Inpatient Primary Treatment programs;

c. doors for privacy and a functional window;

d. adequate personal storage space for each client, including space for hanging clothes and adequate drawer space;

e. a ceiling height of at least seven feet 6 inches in a bedroom space of a size consistent with square footage requirements above, even if part of the room has a ceiling less than 7 feet six inches tall.

f. bed of solid construction, appropriate to size and age of client, that has a clean, comfortable, non-toxic fire-retardant mattress that fits bed. Cots or other portable beds are to be used in emergencies only.

g. clean sheets, pillow, bedspread and blanket provided by the facility as needed or requested by the client unless the request is unreasonable. All linens must be in good repair and systematically removed from use when no longer usable;

h. enough room above the uppermost mattress of any bed to allow the occupant to sit up;

i. a door/escape window leading directly to the outside of the building.

6. Bathrooms. There shall be at least one sink, one tub or shower, and one toilet for every eight residents.

a. Showers and tubs shall have no-slip surfaces and curtains or other safe enclosures.

b. Items required for personal hygiene shall be provided in facilities unless clients are already in possession of such items.

##### **7. Miscellaneous**

a. Personal appliances shall be in good working order and inspected for safety hazards.

b. All clients shall have access to laundry services at reasonable cost or properly maintained laundry facilities.

8. Recreational Equipment. All 24-hour treatment facilities shall have access to reasonable outdoor recreational space and suitable recreational equipment.

9. Vehicles. Transportation shall be provided in a safe and reliable vehicle that is properly licensed, insured, and inspected, and driven by an appropriately licensed person. Vehicles must be adequately insured and operated in accordance with all applicable laws and regulations.

B. Dietary Services. Services are provided on-site under the direction of a qualified dietitian, who is available for telephone consultation whenever client is admitted and has physician orders for dietary restrictions/supplements.

1. General Requirements. The facility shall provide:

a. meal break after five consecutive hours of scheduled activities;

b. an OPH approved kitchen with continuous conditions/procedures to maintain all foods at temperatures and under conditions to assure safe, sanitary handling;

c. nutritious meals of adequate quality and quantity to meet the needs of each client, including religious and dietary restrictions;

d. at least three meals daily, with no more than 14 hours between any two meals;

e. at least an evening snack;

2. Dietitian. The dietitian shall:

a. approve menus and provide written guidelines for substitutions in advance;

b. provide staff in-service training as needed to assure quality meal service;

c. provide information to professional staff regarding dietary needs of specific clients and be available for consultation when necessary.

3. Facility. The facility shall:

a. serve meals in a relaxed atmosphere that promotes utilization of newly learned skills in socialization and communication;

b. maintain sanitation of dishes;

c. ensure that all dishes, cups and glasses used by clients are free from chips, cracks or other defects; and

d. ensure that animals are not permitted in food storage, preparation, and dining areas.

4. Responsibility. Facility retains responsibility to assure that meal preparation/service with client participation meets all requirements listed above and to supervise adequately to ensure compliance.

a. The program shall define duties in writing and have written instructions posted or easily accessible to clients.

b. If menu planning and independent meal preparation are part of the client's treatment program, a licensed dietitian shall:

i. approve the client training curriculum; and

ii. provide training or approve a training program for staff who instruct and supervise clients in meal preparation.

5. Contract Services. Meal preparation/service may be provided by contract service. However, facility is responsible for ensuring that all standards above are met.

C. Adolescent/Children Requirement.

1. Staffing. All requirements are in addition to §7431. a.

Twenty-four-hour facilities require that the qualified professional counselor ratio to clients shall be no higher than 1:8 during waking hours. A minimum of two staff persons shall be present at all times. A qualified

professional counselor shall be on call at all times. Program sponsored activities away from the facility require staff to client ratio no higher than 1:5 with a minimum of two adults at all times.

b. Clients shall be under direct supervision at all times.

i. Onsite, staff shall be readily available at all times, preferably within eyesight or hearing distance. If clients are not within eyesight, staff shall conduct visual checks at least once every hour, including bed checks.

ii. Offsite, clients shall be within eyesight at all times.

2. Educational Resources. Programs for school age children shall provide Department of Education-approved opportunity for clients to maintain grade level and continuity of education during any treatment lasting longer than 14 days unless treatment occurs during school vacation.

3. Physical Plant

a. Residential facilities shall have separate bedrooms and bathrooms for adults and adolescents and for males and females.

b. Adults and adolescents shall not be housed in the same area.

4. Family Communications. The facility shall allow regular communication between an adolescent client and the client's family and shall not arbitrarily restrict any communications without clear, written, individualized clinical justification documented in the client record.

D. Dependent Care. A program that designed to provide substance abuse treatment to mothers with dependant children who remain with parent while the parent is in treatment.

1. Treatment Services

a. Weekly individual and group counseling or family therapy shall be conducted by qualified professional with appropriate experience.

b. Parenting classes shall be provided weekly. Attendance is required.

c. The program shall address the specialized needs of the parent and include services for children.

d. Education, counseling, and rehabilitation services shall address:

i. the effects of chemical dependency on a woman's health and pregnancy;

ii. parenting skills; and

iii. health and nutrition.

e. The program shall have a procedure to regularly assess parent-child interactions. Any identified needs shall be addressed in treatment.

f. Program staff shall provide access to family planning services.

2. Staffing. All requirements are in addition to §7431.

a. Qualified trained professionals shall provide constant supervision appropriate to age of each child.

b. The program shall provide or arrange for child care with a qualified provider while the parent participates in treatment activities. Before supervising children independently, the provider shall have infant CPR certification and at least eight hours training in the following areas:

i. chemical dependency and its impact on the family;

ii. child development and age-appropriate activities;



- iii. child health and safety;
- iv. universal precautions;
- v. appropriate child supervision techniques; and
- vi. signs of child abuse.

c. Every children's program shall have an employee or consultant who is available to provide staff training, evaluate effectiveness of direct care staff, and plan activities, etc. for at least one hour per week per child. This employee shall meet the following educational requirements:

- i. 90 clock hours of education and training in child development and/or early childhood education; and
- ii. one year of documented experience providing services to children.

d. When staff are responsible for children, the staff-to-child ratio shall not exceed 1:3 for infants (18 months and younger) and 1:6 for toddlers and children. Clients shall not supervise another parent's children without written consent from the legal guardian and staff approval.

### 3. Special Considerations

a. Staff shall not allow anyone except the legal guardian or a person authorized by the legal guardian to take a child away from the facility. If an individual shows documentation of legal custody, staff shall record the person's identification before releasing the child.

b. Facility shall have written policy/procedure regarding parent abuse and/or neglect of a child.

c. Residential programs shall not accept dependents over the age of 12 without specific variance approval of OAD and HSS.

d. Children over the age of six shall not share a bedroom with a member of the opposite sex who is not in the child's immediate family.

e. The program shall ensure that children are directly supervised by parents or qualified providers at all times.

f. The program shall have a written policy and a current schedule showing who is responsible for the children at all times.

g. The daily activity schedule shall include a variety of structured and unstructured age-appropriate activities.

h. The program shall provide a variety of age-appropriate equipment, toys, and learning materials.

i. School age children shall have access to school.

j. Standards protecting the health, safety, and welfare of clients also apply to their children.

k. Behavior management shall be fair, reasonable, consistent, and related to the child's behavior. Physical discipline is prohibited.

### 4. Safety Practices

a. The evacuation procedures shall include provisions for children approved by the fire marshal.

b. The program shall not allow children to use:

- i. climbing equipment or swings on or near concrete or asphalt;
- ii. toys that explode or shoot things;
- iii. other sharp or dangerous items; or
- iv. toys and equipment in disrepair.

c. The program shall have safeguards to prevent children from using toys that are dangerous because they are not age-appropriate.

d. The program site shall meet the additional physical plant requirements as required for children.

### 5. Health Practices

a. The program shall have procedures for isolating parents and children who have communicable diseases and providing them with appropriate care and supervision.

b. The program shall keep current immunization records for each child at the program site.

c. The program shall obtain a consent to obtain emergency medical care for each child at admission.

d. Each child shall have an assessment by a medical doctor and/or advanced practice registered nurse within 96 hours of admission. Copies of an assessment performed up to seven days before admission are deemed to meet this requirement.

e. The program shall provide potty chairs for small children and sanitize them after each use.

f. The program shall provide age-appropriate bathing facilities. Infants shall not be bathed in sinks.

g. Staff, volunteers, and parents shall use universal precautions when caring for children other than their own.

h. The program shall ensure that children are clean and appropriately dressed.

i. Staff shall check all diapers frequently, change without delay, and dispose of the diapers in a sealed container and sanitize the changing area.

j. The program shall provide an adequate diet for childhood growth and development, including two snacks per day.

k. Children's medication shall be given according to the label by the parent or a licensed health professional. The facility shall obtain written consent from the parent to administer the medication, as required. The facility shall assume full responsibility for the proper administration and documentation of medication.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1057.1 - 9, redesignated R.S. 40:1058.1 - 9.

HISTORICAL NOTE: Promulgated by 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 26:1473 (July 2000).

### §7447. In-patient Detoxification Programs

A. Types. All requirements are in addition to core requirements.

1. Medically Supported. Professional medical and nursing coverage available as determined by the needs of clients admitted for detoxification in a non-hospital residential setting.

2. Non-medical. Semi-skilled observation, monitoring and treatment by trained para-professionals, for those clients who have been medically approved, and whose detoxification process can be predicted.

NOTE: Medical detoxification is not covered under this licensure as it involves professional level continuous observation, monitoring and treatment for those clients whose detoxification process cannot be predicted due to unstable physical condition or other relevant conditions. Louisiana has only hospital-affiliated medical detoxification programs.

B. Staffing. All requirements are in addition to §7431, unless otherwise noted.

1. Medically Supported Detoxification. Facility shall have qualified professional medical, nursing, and other support staff necessary to provide services appropriate to the needs of clients being admitted to the program.

- a. QPS □ 10 hours per week per 10 clients.
- b. QPC □ 40 hours per week per 10 clients—may be combination of two or more professional disciplines.

2. Non-medical Detoxification—personnel shall consist of professional and other support staff who are adequate to meet the needs of the clients admitted to the facility.

- a. QPS—available by telephone for consultation.
- b. QPC □ 40 hours per week per 25 clients—may be combination of two or more professional disciplines.

3. Designated medical director may be consultative only.

C. Emergency Admissions. The admission assessment process may be delayed only until the client can be interviewed, but no longer than 24 hours unless seen by a physician. Facilities are required to orient direct care employees to monitor, observe and recognize early symptoms of serious illness and to access emergency services promptly.

D. Minimum Standards of Practice

1. History. The program shall obtain enough medical and psycho-social information about the client to provide a clear understanding of the client's present status. Exceptions shall be documented in client record.

2. Medical Clearance/Screening

a. Medically Supported. Medical history and physical examination completed during the 24 hours preceding admission is acceptable, if it is approved by the program's physician or advanced practice nurse. A medical history shall be completed within 24 hours and a physician's examination within 72 hours, unless emergency occurs.

b. Non-medical. Medical screening upon arrival, by First Responder, or equal as reflected in §7423. Health and Safety, with telephone access to RN or MD for instructions for the care of the client.

3. Toxicology/Drug Screening

a. Medically Supported. Physician may waive drug screening if and when client signs list of drugs being abused and understands that his/her dishonesty could result in severe medical reactions during detoxification process.

b. Non-medical. Clients who require drug screening shall be transferred to Medically Supported or Medical Detoxification Program until stabilized.

4. Stabilization Plan. Qualified professional shall identify the client's short term needs based on the detoxification history, the medical history, and the physical examination, if available and prepare a plan of action until client becomes physically stable.

5. Detoxification Plan

a. Medically Supported. The detoxification plan shall be reviewed and signed by the physician and the client, and shall be filed in the client's record within 24 hours of admission with updates as needed.

b. Non-medical. The detoxification plan shall be reviewed and signed by the counselor and the client, and shall be filed in the client's record within 24 hours of admission with updates as needed.

6. Detoxification Notes. The program shall implement the detoxification plan and document the client's response to and/or participation in scheduled activities. Notes shall include:

- a. the client's physical condition, including vital signs;
- b. the client's mood and behavior;

c. client statements about the client's condition and needs; and

d. information about the client's progress or lack of progress in relation to detoxification goals; and

e. additional notes shall be documented as needed.

7. Physicians' Orders When applicable.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1057.1 - 9, redesignated R.S. 40:1058.1 - 9.

HISTORICAL NOTE: Promulgated by 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 26:1476 (July 2000).

**§ 7449. Primary Residential Treatment Programs**

A. General. All requirements are in addition to core requirements. Programs shall include:

1. continuous monitoring, observation, and treatment modalities using the 12-step program design;

2. at least 25 hours of structured treatment activities per week including counseling and educational activities. At least three additional hours must be organized social and/or recreational activities.

B. Staffing. All requirements are in addition to §7431, with the exception of a pharmacist.

1. QPS—shall be on duty as needed, but at least 10 hours per week to assure close supervision and individualized treatment.

2. QPC—counselor shall be on-duty whenever counseling is being provided. If counseling is needed after customary hours, counselor shall be available to be on-duty.

3. Caseload shall not exceed 1:15. Size of counseling groups shall be determined by the needs of clients, but shall not exceed 12 clients.

C. Client Functional Status. Client shall be medically/mentally stable and/or without conditions other than AA/DD that require daily or more frequent monitoring, medications or treatments.

D. Special Requirements. Weekly treatment plan review with documentation by all appropriate disciplines at least once during the first two weeks of treatment.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1057.1 - 9, redesignated R.S. 40:1058.1 - 9.

HISTORICAL NOTE: Promulgated by 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 26:1476 (July 2000).

**§ 7451. Inpatient Primary Treatment**

A. General. All requirements are in addition to core requirements. Programs shall include:

1. Continuous monitoring, observation, and treatment modalities using the twelve-step program design or other models by appropriate medical and psychiatric support personnel.

2. At least 25 hours of structured treatment activities per week including counseling and educational activities. At least three additional hours must be organized social and/or recreational activities, and

3. Non-acute therapeutic regime including medical and psychiatric care, as needed.

B. Staffing. All requirements are in addition to §7431.

1. QPS□15 hours per week per 25 clients to also provide therapy.

2. QPC□40 hours per week per 15 clients.

3. Caseload shall not exceed 1:12 unless prior approved by OAD and HSS.

4. Nursing. Registered nurse is required at least 40 hours per week per 50 clients. Additionally, nursing functions may be supplemented by licensed practical nurses, if a registered nurse or physician is on-duty/on-call in accordance with §7401.

C. Client Functional Status. Clients may require psychiatric and/or medical /nursing care in addition to substance abuse services. Facility may utilize tiered system with client progression to Residential Treatment level of care, however, client must meet the functional status requirements and the facility must designate.

D. Special Requirements

1. Weekly treatment plan review shall be documented by all disciplines involved in care of client to assure continuity of care.

2. Emergency Power. Facilities with capacity greater than 50 clients shall have a reliable, adequately sized emergency power system. The emergency power system is powered by a generator set or battery system, where permitted, to provide power during an interruption of normal electrical service.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1057.1 - 9, redesignated R.S. 40:1058.1 - 9.

HISTORICAL NOTE: Promulgated by 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 26:1477 (July 2000).

#### **§7453. Community-Based Programs**

A. General. All requirements are in addition to core requirements. Programs shall include:

1. transitional living, support and counseling, room and board, social and recreational activities and vocational opportunities;

2. structured, drug-free environment to allow client to maintain or to improve upon the gains made during prior treatment or currently being made in treatment.

3. opportunities for the client to focus on re-socialization and to gradually resume responsibilities associated with independent living.

4. provision of services in Halfway and Three Quarter Houses.

B. Staffing. All requirements are in addition to §7431.

1. QPS-available by telephone for consultation.

2. QPC-counselor must be on-duty when majority of clients are awake and on-site.

Caseload shall not exceed 1: 25 unless prior approved by OAD and HSS.

3. House Manager-non-treatment, direct care person who supervises activities of the facility when the professional staff is on call, but not on duty. This person is required to have adequate orientation and skills to assess situations related to relapse and to provide access to appropriate medical care when needed.

C. Client Functional Status. Clients shall be capable of increasing life responsibilities or be additionally enrolled in primary treatment. If clients are admitted who are also receiving primary treatment, then facility shall meet requirements of Residential Treatment and facility is expected to employ additional professional staff as needed.

D. Special Considerations. Treatment plan review shall be documented in progress notes monthly by all disciplines involved in care of client to assure continuity of care.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1057.1 - 9, redesignated R.S. 40:1058.1 - 9.

HISTORICAL NOTE: Promulgated by 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 26:1477 (July 2000).

#### **§7455. Therapeutic Community (Long Term Residential)**

A. General. All requirements are in addition to core requirements. Facilities shall provide:

1. highly structured environments designed to treat those clients who have demonstrated a pattern of recidivism or a need for long term residential treatment;

2. graduated levels of increasing responsibility, functional capacity, autonomy, privilege, and authority to promote emotional and interpersonal growth through experience or expectation, accountability, support, evaluation, and both favorable and unfavorable consequences for behavior.

B. Staffing. All requirements are in addition to §7431.

1. QPS-additionally, five hours per week to provide supervision and individual treatment as indicated.

2. QPC□40 hours per week per 20 clients.

3. Caseload-not to exceed 1: 20 unless prior approval granted by OAD and HSS.

4. Senior Clients-may be utilized as volunteers to assist in the recovery process, provided that facility staff is on-site and immediately available if needed.

C. Client Functional Status. Upon admission, client must require constant supervision and monitoring to maintain stability.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1057.1 - 9, redesignated R.S. 40:1058.1 - 9.

HISTORICAL NOTE: Promulgated by 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 26:1477 (July 2000).

## RULE

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

Substance Abuse/Addiction Treatment FacilitiesX 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.

#### Title 48

#### PUBLIC HEALTHXGENERAL

#### 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*Xthe 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*Xa program engaged in opioid treatment of individuals with an opioid agonist treatment medication.

\* \* \*

*State Opioid Authority (SOA)*Xthe 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)*Xan 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)*Xan 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 31:0000 (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 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. ...

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 26:1453 (July 2000), LR 31:0000 (March 2005).

#### **§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 31:0000 (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. ...

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 26:1464 (July 2000), LR 31:0000 (March 2005).

#### **§7429. Primary Prevention Programs**

Repealed.

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 26:1465 (July 2000), repealed LR 31:0000 (March 2005).

#### **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.

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 26:1471 (July 2000), LR 31:0000 (March 2005).

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