

DRUG MEDICAL CERTIFICATION STANDARDS
FOR SUBSTANCE ABUSE CLINICS

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I. INTRODUCTION

Substance abuse clinics and their satellite sites wishing to participate in the Drug Medi-Cal (DMC) Program shall be required to be certified by the California Department of Alcohol and Drug Programs (ADP).

- A. DMC certified substance abuse clinics shall be limited to billing DMC for the following modalities of nonresidential treatment services as described in Title 22, California Code of Regulations (CCR), Section 51341.1:
 - 1. Narcotic Treatment Program
 - 2. Outpatient Drug Free Treatment
 - 3. Day Care Rehabilitative Treatment
 - 4. Naltrexone Treatment
- B. In order to participate in the DMC Program for substance abuse treatment services provided within a residential setting, a licensed residential alcoholism or drug abuse recovery or treatment facility shall be DMC certified to provide perinatal residential substance abuse services. DMC certified perinatal residential substance abuse service programs shall be limited to billing DMC for treatment services as described in Title 22, CCR, Section 51341.1.
- C. Services shall only be provided at certified substance abuse clinics and certified satellite sites.

II. DEFINITIONS

- A. "Substance abuse clinic or clinic" means a nonresidential substance abuse treatment program that provides services to individuals who remain less than 24 hours or a perinatal residential substance abuse services program. Services include evaluation, assessment, education, individual and group counseling, replacement narcotic therapy using the medications methadone and/or levoalphacetymethadol (LAAM), naltrexone treatment, treatment planning, treatment outcome goals, and objectives. A substance abuse clinic shall provide substance abuse services more than 20 hours a week. ADP shall conduct an on-site inspection prior to DMC certification.
- B. "OBOT" means an office-based opiate treatment program that is 1) licensed as a narcotic treatment program, pursuant to Section 11877.2(a)(1), Chapter 1, Part 3, Division 10.5, Health and Safety Code, or 2) affiliated and associated with a licensed narcotic treatment program or licensed OBOT, pursuant to Section 11877.2(a)(2), Chapter 1, Part 3, Division 10.5, Health and Safety Code.

An OBOT shall submit proof of authorization by the Narcotic Treatment Program Licensing Branch to provide services and a copy of the physician and/or pharmacy license with the application for DMC certification.

- C. "Satellite site" means a clinic based at a specific building, place, or premises that is at a separate location from a DMC certified substance abuse clinic or an OBOT that is 1) licensed as a narcotic treatment program; or 2) affiliated and associated with a licensed narcotic treatment program or licensed OBOT.

Satellite sites are under the direct administrative and professional supervision of a substance abuse clinic. Satellite sites shall only provide services that the substance abuse clinic of which they are satellites is certified to provide to individuals suffering from substance abuse. A substance abuse clinic that has a satellite site shall provide all of the services that the satellite site is certified to provide. Except for affiliated OBOTS, satellite sites shall be in the same county as the clinic of which they are satellites, shall provide no more than 20 hours a week of substance abuse services, and shall have a director or substance abuse professional on-site a minimum of 4 hours a week. A satellite site that provides substance abuse services for more than 20 hours per week shall obtain certification as a DMC substance abuse clinic. Satellite sites are covered by the DMC certification and provider number issued to the substance abuse clinic of which they are satellites. ADP shall conduct on-site visits to each satellite site prior to DMC certification.

A satellite site that is an OBOT shall maintain affiliation and association with the licensed narcotic treatment program of which it is a satellite; and shall comply with the requirements of Title 9, Division 4, Chapter 4, Subchapters 1-6, California Code of Regulations (commencing with Section 10000.

To obtain certification to provide services at a satellite site, a substance abuse clinic shall submit an application to ADP on a form specified by the Department. The application shall include the name and address of the site, a copy of a valid fire clearance that was conducted by the state Fire Marshal or local fire authority no more than 12 months prior to the date of the application, and a use permit. If the satellite site is a public school site, in lieu of a fire clearance and use permit, the application shall include a letter from the school principal authorizing the provision of services and certifying that all services provided at the public school site meet fire safety rules and regulations. The application shall be maintained by ADP in the DMC certification file. The clinic shall notify ADP, in writing, 30 days in advance of any deletions or additions of satellite sites. Providers cannot be reimbursed for DMC services that were provided at a satellite site prior to the certification of the site by ADP.

- D. "Perinatal residential substance abuse services program" means a 24-hour freestanding residential program which is licensed for a treatment capacity of 16 beds or less. Beds occupied by children who stay in the facility with their mothers are not counted in the 16-bed limit. DMC reimbursable services are limited to pregnant and postpartum women with substance abuse impairments. Services include intake, assessment, diagnosis, evaluation, and individual and group counseling, as well as the required perinatal program elements listed in Title 22, CCR, Section 51341.1. ADP shall conduct an on-site inspection prior to DMC certification.

- E. "Employed staff", for the purpose of these certification standards, shall mean either employed by the organization operating the clinic or contracted by the organization operating the clinic to perform specific duties. The contract shall at least specify duties, hours, period of time and reimbursement for the contracted employee.
- F. "Certification" is a process whereby a provider is found to be eligible to participate in the DMC Program. The process includes an on-site inspection of the clinic to establish eligibility to participate in the DMC Program. The on-site clinic inspection shall be conducted by ADP staff who ascertain whether the provider is in compliance with certification standards.
- G. "Recertification" means the process by which a new certificate is issued to a clinic or satellite site that has been previously certified. Recertification may occur with or without an on-site visit. On-site visits shall be conducted at clinics when any of the following circumstances occur:
1. The clinic changes ownership.
 2. The provider changes the scope of services such that the new services result in more restrictive or higher standards of program services and/or increase treatment hours of clients.
 3. The provider has significant changes in physical plant, i.e., substantial remodeling.
 4. The provider changes address and/or location.
 - a. Except as provided in paragraphs b. and c. below, services provided at the new location shall not be DMC reimbursable until certification of the new site has been completed by ADP. This requires, at a minimum, submitting an application and obtaining and providing to the Department a fire clearance (as described in Section III.A.) and a use permit (as described in Section III.B.).
 - b. To prevent a lapse in certification in the event that the provider moves the operation of the clinic or satellite site to a new location due to an emergency resulting from natural disaster (e.g., flood, earthquake, or other natural disaster that could not have been prevented), building catastrophe (e.g., fire, explosion, plumbing or sewer system damage, vandalism), health and safety issue (e.g., epidemic, outbreak of disease), or a 60-day or less notice of loss of lease, the provider shall, prior to the move, notify ADP of the necessity of the move and the address where the clinic or satellite site will be relocating. Within 60 days after the date of the move, the provider shall submit to ADP an application for certification including a fire clearance (as described in Section III.A.) and a use permit (as described in Section III.B.), description of the emergency necessitating the move, and a statement affirming that there is no change to the program other than the relocation due to emergency. If the provider fails to comply with this requirement, clinic certification shall terminate as of the 61st day after

the date of the move.

- c. In the event that a temporary emergency is declared by the county emergency services officer that would prevent the delivery of services at the certified site (e.g., a rolling electrical blackout), the provider may provide services at a location other than the certified site. Within 24 hours of providing the service, the provider shall notify ADP of the necessity and duration for providing the service off-site and the address where the service was provided.

The provider shall notify ADP at least 60 days prior to any occurrence of the items listed in 1 through 4 above. Failure to provide ADP with 60 days advance notification or complete documentation may result in suspension from participation in the Medi-Cal program.

On-site inspections are not limited to purposes of recertification, but may be conducted for reasonable cause.

- H. "Decertification" means termination of DMC certification which occurs as a result of any of the following circumstances:

1. The provider sells or otherwise transfers the clinic or property of the clinic as identified on the certification, unless the transfer of ownership applies to the transfer of stock when the clinic is owned by and certified as a corporation, and when the transfer of stock does not constitute a majority change in ownership.
2. The provider fails to provide ADP with a copy of a valid fire clearance within the time frame specified in Section III.A. following a change in ownership of an existing DMC certified clinic.
3. The provider surrenders the clinic certification to the Department.
4. The clinic provider is a sole proprietor and the sole proprietor dies.
5. The provider actually or constructively abandons the certified clinic. Constructive abandonment includes insolvency, eviction, or seizure of assets or equipment resulting in the inability to provide Drug Medi-Cal services.

- I. "Under the direction of a physician" means a physician formulation of, approval of, or involvement in each DMC patient's plan of care. Such direction may take one of several forms, such as development or review/approval of the treatment plan of care, clinical consultation on the patient's case medication evaluation, or involvement in the patient's case conference. Evidence of the physician's direction shall be documented by the physician's notations and signature in the patient's health record and treatment plan in accordance with Title 22, CCR, Section 51341.1(h)(2)(A), or for narcotic treatment programs, Title 9, CCR, Section 10305, as specified in Title 22, CCR, Section 51341.1(h)(2)(B).

- J. "Postpartum" means the 60-day period beginning on the last day of pregnancy, regardless of whether other conditions of eligibility are met. Eligibility of Medi-Cal beneficiaries who are postpartum ends on the last day of the calendar month in which the 60th day occurs.
- K. "Perinatal certification" means an enhanced type of DMC certification for a clinic that provides the following additional services for pregnant and postpartum women:

1. Mother/Child Habilitative and Rehabilitative Services

Perinatal clinics provide habilitative services that include interactive parenting skills building and child development training. The provider may hire staff specifically for these duties, or they may be incorporated into the duties of other positions (e.g., counselor). Parenting skills building and child development staff shall provide the mothers with positive role modeling, education, instruction and structured activities. At no time shall staff provide child care.

The interactive skills building and child development training can be provided through the program's on-site cooperative child care component. On-site cooperative child care is defined by the following elements:

- a. Child development staff provide the mothers with parenting skills training, child development education, and supportive role modeling;
- b. The mothers are on-site and the children are under their care and supervision; and
- c. The number of children is limited to 12 or less at any one time. For more information on cooperative child care, refer to the California Health and Safety Code, Section 15986.792.

Child care also may be provided through on-site licensed child care or off-site licensed child care for the children of clients receiving treatment, however, Perinatal DMC will not reimburse clinics for the cost of licensed child care whether it is provided on- or off-site.

2. Service Access

Perinatal clinics shall provide or arrange for transportation to and from medically necessary treatment and other Medi-Cal covered services, such as primary medical care and pediatric care, for pregnant and postpartum women who do not have their own transportation.

3. Education

Pregnant and postpartum women require medically necessary prevention and education intervention to reduce harmful effects of alcohol and drugs on mother and fetus or mother and infant. Perinatal clinics shall provide education and training on:

- a. The impact of substance abuse during pregnancy;
- b. The impact of substance abuse while breast feeding;
- c. Environmental impact of substance abuse on infant;
- d. HIV/AIDS transmission and access to testing; and
- e. Tuberculosis and access to testing.

4. Coordination of Ancillary Services

Pregnant and postpartum women shall receive medically necessary assistance to access and complete required appointments to ancillary services, such as other medical services, dental services, necessary social services, community services, and educational/vocational training.

III. GENERAL REQUIREMENTS

Participation in the DMC Program is contingent upon compliance with the following requirements:

A. Fire Safety

Each clinic shall conform with the rules and regulations adopted by the State Fire Marshal and the requirements of the local fire authority having jurisdiction. Each clinic that is applying for DMC certification or adding a satellite site shall obtain and provide ADP with a copy of a valid fire clearance that has been conducted by the State Fire Marshal or local fire authority no more than 12 months prior to the date of the application for certification.

When a DMC certified clinic changes ownership and continues to provide services at the same site, the new owner shall have up to 90 days after the date of DMC certification to obtain and provide ADP with a copy of a valid fire clearance. Each clinic shall maintain a valid fire clearance from the State Fire Marshal or fire authority having jurisdiction. In lieu of a fire clearance, a clinic that is located at a public school site may provide a letter from the school principal that certifies that all services provided at the public school site meet fire safety rules and regulations.

B. Use Permits

Approval, as necessary, shall be secured by the local agency authorized to provide a building use permit. If the local agency authorized to provide a building use permit does not require a use permit, the clinic shall obtain a letter from the local agency attesting to the circumstances. In lieu of a local use permit, a clinic or satellite site that operates on a public school campus shall obtain a letter authorizing the provision of services at the public school from the school principal.

C. Accessibility of Service

Services shall be accessible to the disabled.

D. Physical Plant

The clinic shall be clean, sanitary, and in good repair at all times. Maintenance shall include provisions and surveillance of maintenance services and procedures for the safety and well-being of patients, personnel, and visitors (Health and Safety Code, Sections 208(a) and 1275).

E. Utilization Review (UR)

The provider shall establish, implement, and maintain procedures in accordance with Title 22, CCR, Section 51341.1.

F. Patient Health Records

1. Each provider shall establish and maintain a patient health record on every patient admitted for care at the clinic.
2. All health records of discharged patients shall be completed and filed in a secure and confidential location within 30 days after discharge, and such records shall be kept for a minimum of three years, in accordance with Title 22, CCR, Section 51341.1 (i).
3. Information contained in health records shall be confidential and shall be disclosed only to authorized persons in accordance with federal, state, and local laws. (Title 9, CCR, Section 10155)

G. Administrative Policies

Written administrative policies shall be implemented, maintained, reviewed annually and revised as necessary. The policies shall include:

1. Policies and procedures governing patient health records.
2. Personnel Files

Personnel files shall be maintained on all employees and shall contain:

- a. Application for employment and/or resume;
- b. Employment confirmation statement;
- c. Salary schedule and salary adjustment information;
- d. Evaluations of employee;
- e. Health records as required; and

- f. Other personnel actions (e.g., commendations, discipline, status change, employment incidents and/or injuries).
- 3. Procedures shall be established for access to and confidentiality of personnel records.
- 4. Job descriptions shall be developed, revised as needed, and approved annually by the governing body. The job descriptions shall include:
 - a. Position title and classification;
 - b. Duties and responsibilities;
 - c. Lines of supervision, (if applicable);
 - d. Education, training, work experience and other qualifications for the position.
- 5. A written code of conduct for employees and volunteers shall be established which addresses at least the following:
 - a. Use of drugs and/or alcohol;
 - b. Prohibition of sexual contact with clients; and
 - c. Conflict of interest.

H. Health Records

Health screening and health records shall be maintained for persons working in the clinic.

- 1. All persons working in the clinic, including volunteers, shall have a health screening within six months prior to employment or within 15 days after employment.
- 2. The provider shall maintain a health record of each employee which includes reports of all employment-related health examinations. These records shall be kept for a minimum of three years following termination of employment.
- 3. All persons working in the clinic shall have been screened and those who are found to have symptoms of infectious disease shall be removed from contact with patients.

I. Drugs

If the provider maintains, administers, or dispenses drugs, the drug distribution service shall be in conformance with all appropriate state and federal pharmacy laws (see Section VI. below).

J. Basic Services

The following basic services shall be provided by all DMC substance abuse clinics:

1. A DSM-III or DSM-IV diagnosis and evaluation toward formulation of a continuing treatment plan.
2. A medication maintenance program, if appropriate.
3. Individual and/or group therapy or counseling.

IV. STAFF

A. Medical Director/Medical Responsibility

1. Each substance abuse clinic shall have a licensed physician designated as the medical director. All medical services provided by the substance abuse clinic shall be under the direction of a physician, who shall be available on a regularly scheduled basis and otherwise on call. The medical director shall assume medical responsibility for all patients. The medical director shall direct medical services, either by acting alone or through an organized medical staff.
2. The medical director's responsibilities, acting alone or through an organized medical staff, shall include:
 - a. Establishing, reviewing, and maintaining medical policies and standards.
 - b. Assuring the quality of medical services given to all patients.
 - c. Assuring that at least one physician practicing at the clinic shall have admitting privileges to a general acute care hospital or a plan, as approved by ADP, for ensuring needed hospital services. For narcotic treatment programs, this requirement is the responsibility of the program sponsor and shall be met by the program sponsor entering into an agreement with a hospital official to provide general medical care in accordance with Title 9, CCR, Section 10340.
 - d. Assuring that a physician has assumed medical responsibility for all patients treated by the clinic (Title 9, CCR, Section 10110).
3. Documentation of assumption of medical responsibility shall include, but not be limited to, written approval of the treatment plan in accordance with Title 22, CCR, Section 51341.1 (h)(2)(A), or for narcotic treatment programs, Title 9, CCR, Section 10305, as specified in Title 22, CCR, Section 51341.1(h)(2)(B).

B. Clinic Director

The clinic staff, professional and nonprofessional, shall be under the administration of the clinic director.

C. Substance Abuse Professional

1. Each substance abuse clinic shall have one or more substance abuse professionals.
2. A substance abuse professional is defined as a person who has completed an Associate of Arts degree and one year of experience, or has three years experience in a mental health or substance abuse setting. Experience in a

mental health or substance abuse field may be substituted for the degree requirement on a year-for-year basis provided that the experience includes clinical evaluation, treatment planning, and individual and group counseling.

3. A substance abuse professional shall provide the following medically necessary, clinical services prescribed for patients admitted, registered, or accepted for care by the clinic:
 - a. Individual and group counseling.
 - b. Crisis intervention.
 - c. Collateral services.
4. A substance abuse professional shall document and review patient progress; and prepare treatment and discharge plans and discharge summaries.

D. Minimum Staff Requirements

Each clinic shall be staffed by a medical director, clinic director, and substance abuse professional. If qualified, one person may serve in all three positions-- medical director, clinic director, and substance abuse professional. The staff may also include other qualified professionals and counselors which may include psychiatric technicians, registered nurses, licensed vocational nurses, nurse practitioners, physician's assistants, or other nonphysician practitioners. Narcotic treatment programs shall be staffed by a licensed nurse or other individual lawfully authorized to administer medication.

E. Clinic Staff

Clinic staff shall furnish the services prescribed for patients admitted for care by the clinic. The clinic staff shall be qualified in accordance these standards and current legal, professional, and technical standards, and appropriately licensed, registered, or certified where required.

V. CERTIFICATION REQUIREMENTS

- A. Certification shall be granted to clinics upon full compliance with all DMC regulations and standards.
 1. Noncompliance means: a deficiency in meeting any of the standards or failure to comply with any of the regulations cited above.
 2. Statement of deficiencies means: a written statement of all deficiencies noted by ADP at the time of the on-site inspection.
 3. Plan of correction means: a written response by the clinic, submitted to ADP within 30 days of receipt of the statement of deficiencies, which includes:

- a. A description of how and when deficiencies were corrected.
 - b. A description of the method of monitoring to prevent recurrence of deficiencies and ensure ongoing compliance with the standards and regulations.
4. The review of an application for DMC certification shall be terminated if a provider does not submit a plan of correction within 30 days of receipt of the statement of deficiencies. A provider may re-apply anytime after an application has been terminated.

VI. PHARMACEUTICAL SERVICE REQUIREMENTS

If the clinic maintains, administers, or dispenses drugs, the drug distribution service shall be in conformance with all appropriate state and federal pharmacy laws.

A. Orders for Drugs

No drugs shall be administered except upon the order of a person lawfully authorized to prescribe for and treat human illness. All such orders shall be in writing and signed by the person giving the order. The name, quantity or duration of therapy, dosage, and time of administration of the drug, the route of administration if other than oral, and the site of injection when indicated shall be specified. Prescription orders may be given by telephone to a licensed pharmacist, licensed nurse, registered nurse, or licensed psychiatric technician and shall be immediately recorded in the patient's health record. The prescription order shall be signed by the prescriber within 72 hours.

B. Labeling and Storage

Labeling and storage of drugs shall comply with the following:

1. Containers which are cracked, soiled, or without secure closures shall not be used. Drug labels shall be legible.
2. All drugs obtained by prescription shall be labeled in compliance with state and federal laws governing prescription dispensing. No person other than a pharmacist or a physician shall alter any prescription label.
3. Nonlegend drugs shall be labeled in conformance with state and federal food and drug laws.
4. Test reagents, germicides, disinfectants, and other household substances shall be stored separately from drugs.
5. External use drugs in liquid, tablet, capsule, or powder form shall be stored separately from drugs for internal use.
6. Drugs shall be stored at appropriate temperatures based on the manufacturer's product insert. When drugs are stored in the same refrigerator with food, the drugs shall be kept in a closed, properly labeled container clearly labeled "DRUGS."

7. Drugs shall be stored in an orderly manner in cabinets, drawers, or carts of sufficient size to prevent crowding.
8. Drugs shall be accessible only to personnel designated in writing by the clinic director.
9. Drugs shall not be kept in stock after the expiration date on the labels, and no contaminated or deteriorated drugs shall be available for use.
10. The drugs of each patient shall be kept and stored in their original individual received containers. No drug shall be transferred between containers, with the exception of take-home bottles.

C. Disposal of Drugs

Disposal of drugs shall meet all applicable state and federal requirements.

D. Dispensing of Drugs

Drugs shall only be dispensed by a physician, pharmacist, or those persons lawfully authorized to do so. Drug dispensing shall be in compliance with all applicable laws and regulations.

1. Drugs shall be administered as prescribed and shall be recorded in the patient's health record.
2. Drugs shall be administered only by those persons lawfully authorized to do so.