65D-30.014 Standards for Medication-Assisted ~~and Methadone Maintenance~~ Treatment for Opioid Addiction.

In addition to Rule 65D-30.004, F.A.C., the following standards apply to Methadone Medication-Assisted ~~and Methadone Maintenance~~ Treatment unless otherwise stated.

(1) State Authority. The state authority is the D~~d~~epartment's Office of Substance Abuse and Mental Health ~~Program Office~~.

(2) No change.

(3) Determination of Need.

(a) Criteria. New providers shall be established only in response to the D~~d~~epartment's determination of need, which shall occur annually. The determination of need shall only apply to methadone medication-assisted ~~and methadone maintenance~~ treatment. To ~~In its effort to~~ determine need, the D~~d~~epartment shall examine the factors and perform the assessment detailed in "The Methodology of Determination of Need Methadone Medication-Assisted Treatment," CF-MH 4038, March 2018, ~~incorporated~~ by reference and available at http://www.flrules.org/Gateway/reference.asp?No=Ref-XXX. ~~information on treatment, the consequences of the use of opioids (e.g., arrests, deaths, emergency room mentions, other incidence and prevalence data that may have relevance at the time, etc.), population and data on treatment accessibility.~~

(b) Procedure. The D~~d~~epartment shall publish the results of the assessment in the Florida Administrative Weekly by June 30. The publication shall direct interested parties to submit applications for licensure to the Substance Abuse and Mental Health Program Office ~~department's district~~ where need has been demonstrated and shall provide a closing date for submission of applications. Methadone medication-assisted treatment facilities must open within two (2) years of receiving approval. ~~The district office shall conduct a formal rating of applicants on a form titled MEDICATION AND MAINTENANCE TREATMENT NEEDS ASSESSMENT, September 6, 2001, incorporated herein by reference. The form may be obtained from the Department of Children and Family Services, Substance Abuse Program Office, 1317 Winewood Boulevard, Tallahassee, Florida 32399-0700.~~

~~Should the number of responses to the publication for a new provider exceed the determined need, the selection of a provider shall be based on the following criteria:~~

~~1. The number of years the respondent has been licensed to provide substance abuse services;~~

~~2. The organizational capability of the respondent to provide medication and methadone maintenance medication-~~

~~assisted treatment in compliance with these rules; and~~

~~3. History of substantial noncompliance by the respondent with departmental rules;~~

(4) General Requirements.

(a) Medication-Assisted Treatment Program ~~or Methadone Maintenance~~ Sponsor. The sponsor, as defined in 65D-30.002(X), of a new provider shall be a licensed health professional and shall have worked in the field of substance use ~~abuse~~ treatment at least five (5) years. The sponsor is responsible for the program operation and 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.

(b) Medical Director. The medical director of a provider shall have a minimum of two (2) years' experience in the field of substance use ~~abuse~~ treatment.

(c) Special Permit and Consultant Pharmacist.

1. Special Permit.

a. All providers ~~facilities that distribute methadone or other medication~~ shall obtain a special pharmacy permit from the State of Florida Board of Pharmacy. New applicants shall be required to obtain a special pharmacy permit prior to licensure by the D~~d~~epartment.

b. No change.

2. Consultant Pharmacist. The responsibilities of the consultant pharmacist, if applicable, include the following:

a. Develop policies and ~~operating~~ procedures relative to the supervision of the compounding and dispensing of all medications ~~drugs~~ dispensed in the facility ~~clinic~~;

b. Provide ongoing pharmaceutical consultation;

c. Develop operating procedures for maintaining all medication ~~drug~~ records and security in the area within the facility in which the compounding, storing, and dispensing of medications ~~medicinal drugs~~ will occur;

d. No change.

e. Prepare written reports regarding the provider's level of compliance with established pharmaceutical procedures. Reports shall be prepared at least semi-annually and submitted, signed and dated by the consultant pharmacist and submitted to the medical director; and~~;~~

f. Physically v~~V~~isit the provider ~~facility~~ at least every two (2) weeks to ensure that established procedures are

being followed, unless otherwise stipulated by the state Board of Pharmacy. A log of such visits shall be maintained, ~~and~~ signed and dated by the consultant pharmacist at each visit.

3. Change of Consultant Pharmacist. The provider's medical director shall notify the Board of Pharmacy within 10 days of any change of consultant pharmacists, and provide a copy of such notification to the Substance Abuse and Mental Health Program Office and the State Opioid Treatment Authority (SOTA).

(d) Providers shall develop policies and procedures for the treatment of pregnant women. ~~Pregnancy and Medication and Methadone Maintenance~~.

1. Use of Methadone.

a. Prior to the initial dose, each female ~~client~~ shall be fully informed of the ~~possible~~ risks of taking and not taking ~~from the use of~~ methadone during pregnancy, including possible adverse effects on the mother or fetus. ~~and shall be told that safe use in pregnancy has not been established in relation to possible adverse effects on fetal development.~~ If the medication is not taken, risk includes withdrawal syndrome which has been associated with fetal demise. The individual ~~client~~ shall sign and date a statement acknowledging this information. Pregnant women shall be seen by the physician or their qualified designee as clinically advisable. The physician or qualified medical designee must document in the clinical record that the pregnant individual was informed of the risks in this paragraph.

b. Pregnant individuals ~~clients~~ shall be informed of the opportunity and need for prenatal care ~~either by the provider or~~ by referral to ~~other~~ publicly or privately funded health care providers. ~~In any event, t~~The provider shall establish a documented system for referring individuals ~~clients~~ to prenatal care.

c. In the event ~~If~~ there are no publicly funded prenatal referral resources to serve those who are indigent, or if the ~~provider cannot provide such services, or if the client~~ individual refuses the services, the provider shall offer her basic prenatal instruction on maternal, physical, and dietary care as part of its counseling service. The nature of prenatal support shall be documented in the clinical ~~client~~ record.

d. When the individual ~~If the client~~ is referred for prenatal services, the practitioner to whom she is referred shall be notified that she is undergoing methadone ~~maintenance~~ medication-assisted treatment and provided treatment plans addressing pregnancy and post-partum care. Documentation of referral shall be kept in the clinical record. If a pregnant individual ~~client~~ refuses ~~prenatal care or~~ referral and prenatal instruction and counseling, the provider shall obtain a signed statement from the individual ~~client~~ acknowledging that she had the opportunity for the prenatal care but declined ~~refused it~~.

e. The physician shall sign or countersign and date all entries related to prenatal care.

f. Treating physicians or their qualified designee shall consult with other treating medical staff providing care and medications to ensure that prescribed medication protocols are not contraindicated.

2. Use of Other Medication During Pregnancy. Providers shall adhere to the prevailing federal and state requirements regarding the use of opioid treatment medications ~~medication~~ other than methadone in the ~~maintenance~~ treatment of individuals ~~clients~~ who are or become pregnant during the course of treatment.

(e) Minimum Responsibilities of the Physician. Physicians must adhere to best practice standards, regardless of the type of medication used, for an individual receiving medication-assisted treatment for opioid addiction. Best practices mean practices that meet or exceed the standards established by nationally-recognized, research-validated substance use disorder-specific program standards regarding the types of services, hours of clinical care, and credentials of staff for levels of care. In addition, t~~T~~he responsibilities of the physician include the following:

1. To ensure that evidence of current physiological addiction, history of addiction, and exemptions from criteria for admission are documented in the clinical ~~client~~ record before the individual ~~client~~ receives the initial dose of ~~methadone or other~~ medication;~~,~~

2. To sign or countersign and date all medical orders, including the initial prescription, all subsequent prescription changes, and all changes in the frequency of take-home medication; ~~methadone, and the prescription of additional take-home doses of methadone in cases involving the need for exemptions,~~

3. To ensure that justification is recorded in the clinical ~~client~~ record for any change to the ~~reducing the~~ frequency of visits to the provider for observed drug ingesting, ~~providing additional take-home methadone in cases involving the need for exemptions,~~ including cases involving the need for exemptions, or when prescribing medication for physical or emotional problems; ~~and~~

4. To review, sign or countersign, and date treatment plans at least annually; and~~.~~

5. To ensure that a face-to-face assessment is conducted with each individual ~~client~~ at least annually, including evaluation of the individual's physical/medical status, ~~client's~~ progress in treatment, and justification for continued maintenance or medical clearance for voluntary withdrawal or a dosage reduction protocol. The assessment shall be conducted by a physician or a P.A. or A.R.N.P. under the supervision of a physician. If conducted by authorized staff other than a physician, the assessment shall be reviewed and signed by a physician in accordance with the medical protocol established in subsection 65D-30.004(7), F.A.C. The protocol shall include criteria and the conditions under

which the assessment would be conducted more frequently.

(f) Central ~~Client~~ Registry.

1. Providers shall register and participate in the Department-approved electronic ~~regional~~ registry system for individuals receiving methadone medication-assisted treatment services. The registry is used to prevent the enrollment of individuals at more than one (1) provider and to facilitate continuity of care in the event of program closure and guest dosing verification. The registry shall be implemented in compliance with 42 Code of Federal Regulations, Part 2. The provider must submit to information gathering activities by the SOTA for state planning purposes. ~~activities for the purpose of sharing client identifying information with other providers located within a 100-mile radius, to prevent the multiple enrollment of clients in more than one provider. Each regional registry shall be conducted through an automated system where this capability exists. In those instances where the development and implementation of an automated system would require additional technology, an alternative method shall be used on an interim basis, as long as the alternative is implemented in compliance with 42 Code of Federal Regulations, Part 2, and approved by the state authority shall designate a provider.~~

2. Providers must maintain the registry by recording and updating identifying, demographic, emergency contact, dosing and relevant medical information for all individuals receiving methadone medication-assisted treatment.

a. Each business day, providers shall monitor individuals enrolled in more than one (1) site and discharge any individuals attempting to enroll in another location. Individuals shall not be dual enrolled in any two (2) locations for longer than three (3) days. Providers shall monitor the following reports quarterly to ensure compliance with no higher than a five (5) percent rate for missing data for the following data reports:

i. Missing Photos.

ii. Missing Zip Codes.

iii. Missing Dosing Summary.

iv. Missing Mileage Information.

v. Missing County Information.

vi. Missing Emergency Medication Information.

vii. Missing Admit Forms.

b. Providers shall monitor the following reports quarterly and ensure data is accurate:

i. Pregnancy Status. Providers must maintain accurate data on pregnancy status.

ii. Emergency Consent. Providers must make monthly attempts to add emergency contact for individuals who have not provided consent to be contacted during an emergency clinic closure. Refusals must be documented. Providers shall ensure accuracy of emergency contact information quarterly.

iii. Emergency Dosing Projected Inventory Requirements. Providers must ensure they have adequate methadone stored in the event of an emergency.

~~Providers may volunteer to coordinate the registry activities or, in the event that no provider volunteers, the state authority shall designate a provider.~~

3. Program directors must certify monthly, via Central Registry, the accuracy of census data. ~~Providers shall submit, with the application for licensure, written plans for participating in registry activities.~~

4. Methadone or other opioid treatment medication shall not be administered or dispensed to an individual ~~a client~~ who is known to be currently enrolled with ~~participating in~~ another provider. ~~5.~~ The individual ~~client~~ shall always report to the same provider unless prior approval is obtained from the original provider for treatment at another provider. Permission to report for treatment with ~~at the facility of~~ another provider shall be granted only when the multi-disciplinary treatment team, in their professional judgement, determine it is in the best interest of the individual. The permission, supporting clinical documentation, and evidence of a warm handoff ~~in exceptional circumstances and~~ shall be noted in the clinical ~~client's~~ record. Upon notification that an individual is being admitted to a new provider, it is the responsibility of the original admission site to discharge an individual from Central Registry.

5~~6~~. Individuals applying for methadone medication-assisted ~~maintenance~~ treatment shall be informed of the registry procedures and shall be required to sign a consent form before receiving services. Individuals who apply for services and do not consent to the procedures will not be enrolled ~~placed in medication-assisted treatment maintenance~~.

6~~7~~. If an individual is found trying to secure or has succeeded in obtaining duplicate doses of methadone or other medication, the individual ~~client~~ shall be referred back to the original provider. A written statement documenting the incident shall be forwarded to the original provider and, if the individual succeeded in obtaining the duplicate dose, the incident must be reported in the Department-approved incident reporting system by the provider who dispensed the duplicate dose. The physician of the original provider shall evaluate the individual ~~client~~ as soon as medically feasible for continuation of treatment. In addition, a record of violations by individuals ~~individual clients shall~~ must become part of the clinical record maintained by all participating providers and shall be made available to Department staff upon request ~~in an automated system and permit access by all participating providers~~.

7. Providers shall submit with the application for licensure written plans for participating in registry activities, maintaining accurate data on staff and individuals in treatment, and ensuring annual training for all staff on reporting and disaster preparedness procedures.

8. It is the responsibility of the SOTA to run quarterly reports to identify providers with missing data related to patient identification, dosage information, dual enrollment, pregnancy outcomes, and demographic information. Providers with a higher than five (5) percent non-compliance rate (missing or inaccurate data) will be contacted by the SOTA and/or licensure staff. Pursuant to s. 397.415, F.S., a Class IV fine will be imposed on those providers who do not correct non-compliance issues within five (5) days.

9. Prior to conducting an inspection or program review, an authorized agent of the Department shall contact the SOTA to obtain a compliance report. Non-compliance shall be incorporated into inspection reports and included in corrective action plans.

(g) Wait lists.

1. Providers must maintain wait list data for individuals seeking care but unable to enroll within 24 hours of first contact requesting initiation of treatment.

2. When an opening is available, providers must make at last one (1) attempt to contact the next prospective individual on the waiting list and maintain a system of documenting attempts. Documentation shall include at a minimum: date of request, individual's name, date of birth, address, and contact information.

(h)~~(g)~~ Operating Hours and Holidays

1. Providers shall post operating hours in full view of the public ~~a conspicuous place within the facility~~. This information shall include hours for counseling and administering medication ~~medicating~~ ~~clients~~.

2. All providers shall be open Monday through Saturday. Providers shall have medicating hours and counseling hours that accommodate individuals ~~clients~~, including two (2) hours of medicating time accessible daily outside the hours of 9:00 a.m. to 5:00 p.m.

3. Providers are required to medicate on Sundays according to the needs of the individual ~~client's needs.~~ This includes individuals ~~would include clients~~ on Phase 1, individuals ~~clients~~ on a 30 to 180-day detoxification regimen, and individuals ~~clients~~ who need daily observation. The provider shall develop ~~operating~~ policies and procedures for Sunday coverage.

4. In case of impending disaster, providers shall implement disaster preparedness policies and procedures as

necessary regarding operating hours and dosing.

5. When holidays are observed, all individuals ~~clients~~ shall be given a minimum of a seven (7)-day notice of any changes to the hours of operation.

6. When applying for a license, providers shall inform the respective program ~~district~~ offices of their intended holidays. In no case shall two (2) or more holidays occur in immediate succession unless the provider is granted an exemption by the state and federal authority. Take-out privileges shall be available to all eligible individuals ~~methadone clients~~ during holidays, ~~but only~~ if clinically advisable. ~~On those days during which the provider is closed, s~~Services shall be accessible to individuals ~~clients~~ for whom take-home medication ~~out methadone~~ is not clinically advisable. Individuals ~~Clients~~ who fall into this category shall receive a minimum of seven (7) days ~~adequate~~ notification regarding arrangements and ~~the~~ exact hours of operation.

(5) Maintenance Treatment Standards.

(a) Standards for Placement.

1. Determining Addiction and Placement.

a. An individual ~~A person~~ aged 18 or over shall be placed in treatment ~~as a client~~ only if the physician, or their qualified designee identified in accordance with the medical protocol established in subsection 65D-30.004(7), F.A.C., determines that the individual ~~person~~ is currently physiologically addicted to opioid drugs and became physiologically addicted at least one (1) year before placement in medication-assisted ~~maintenanc~~e treatment.

b. A one (1)-year history of addiction means that individuals seeking ~~an applicant for~~ placement in medication-assisted ~~maintenance~~ treatment were ~~was~~ physiologically addicted to opioid drugs at least one (1) year before placement and were ~~was~~ addicted continuously or episodically for most of the year immediately prior to placement with ~~in~~ a provider.

c. In the event the exact date of physiological addiction cannot be determined, the physician or their qualified designee, may admit the individual ~~person~~ to ~~maintenance~~ treatment if, by the evidence presented and observed, and utilizing reasonable clinical judgment, the physician or their qualified designee concludes ~~it is reasonable to conclude~~ that the individual ~~person~~ was physiologically addicted during the year prior to placement. Such observations shall be recorded in the clinical ~~client~~ record by the physician or their qualified designee. ~~Participation in treatment must be voluntary.~~

d. Individuals with a chronic immune deficiency or who are pregnant must be screened and admitted on a priority

basis.

e. Individuals seeking admission with only a primary medical diagnosis of a chronic pain condition must be referred to specialists qualified to treat chronic pain conditions and are not eligible for admission.

2. Placement of Individuals Under 18 Years of Age

a. An individual ~~A person~~ under 18 is required to have had two (2) documented unsuccessful attempts at short-term detoxification or substance use ~~drug-free~~ treatment within the last year to be eligible for ~~maintenance~~ treatment.

b. The physician or their qualified designee shall document in the clinical ~~client's~~ record that the individual ~~client~~ continues to be or is again physiologically dependent on opioid drugs and is appropriate for placement. ~~No person under 18 years of age shall be placed in maintenance treatment unless a parent, legal guardian, or responsible adult provides written consent.~~

c. Treatment standards in this rule are not intended to limit current best practice protocols for this population.

3. Evidence of Addiction.

a. In determining the current physiological addiction of the individual ~~client~~, the physician or their qualified designee shall consider signs and symptoms of drug intoxication, evidence of use of drugs through a urine drug screen, and needle marks.

b. Other evidence of current physiological dependence shall be considered by noting early signs of withdrawal such as cramping, lachrymation, rhinorrhea, pupillary dilation, pilo erection, body temperature, pulse rate, elevated blood pressure, and increased respiratory rate.

(b) Individual Consent.

1. Individuals shall be advised of the benefits of therapeutic and supportive rehabilitative services, and that the goal of methadone medication-assisted treatment is stabilization of functioning. The individual shall be fully informed of the risks and consequences of methadone medication-assisted treatment.

2. Each provider shall provide a thorough explanation of all program services, as well as state and federal policies and regulations, and obtain a voluntary, written and signed program-specific statement of fully informed consent from the individual at admission.

3. In full consultation with the individual, the counselor shall discuss present level of functioning, course of treatment, and future goals. Consultations shall occur, at a minimum, quarterly for individuals in year one of treatment, and at a minimum, bi-annually for individuals in treatment longer than one year. These discussions should not place

pressure on the individual to withdraw from or to remain in methadone medication-assisted treatment, unless medically or clinically indicated. Acknowledgement of these discussions shall be documented in the clinical record.

4. No individual under 18 years of age shall be placed in methadone medication-assisted treatment unless a parent or legal guardian provides written consent.

(c)~~(b)~~ Exemption from Minimum Standards for Placement.

1. An individual ~~A person~~ who has resided in a penal or chronic-care institution for one (1) month or longer may be placed in ~~maintenance~~ treatment within 14 days before release or within 6 months after release from such institution. This can occur without documented evidence to support findings of physiological addiction, providing the individual ~~person~~ would have been eligible for placement before incarceration or institutionalization, and in the reasonable clinical judgment of the physician or their qualified designee, methadone medication-assisted treatment is medically justified.

2. ~~Documented e~~Evidence of prior residence in a penal or chronic-care institution, evidence of all other findings, and the criteria used to determine the findings shall be recorded by the physician or their qualified designee in the clinical ~~client~~ record.

3. The physician or their qualified designee shall sign and date these entries ~~recordings~~ before the initial dose is administered.

(d) Pregnant individuals.

1~~2~~. Pregnant individuals ~~clients~~, regardless of age, who have had a documented addiction to opioid drugs in the past and who may be in direct jeopardy of returning to opioid drugs, may be placed in methadone medication-assisted treatment. ~~with all its attendant dangers during pregnancy, may be placed in maintenance treatment.~~ For such individuals ~~clients~~, evidence of current physiological addiction to opioid drugs is not needed if a physician or their qualified designee certifies the pregnancy and, in utilizing reasonable clinical judgment, finds treatment to be medically justified.

2. Pregnant individuals ~~clients~~ may be placed on a medication-assisted ~~maintenance~~ treatment regimen using a medication other than methadone only upon the written order of the physician who determines this to be the best choice of therapy for that individual ~~client~~.

3. ~~Documented e~~Evidence of current or prior addiction and criteria used to determine such findings shall be recorded in the clinical ~~client~~ record by the admitting physician or their qualified designee. The physician or their

qualified designee shall sign and date these recordings prior to administering the initial dose.

(e) Readmission to Treatment.

1~~3~~. Up to 2 years after discharge or detoxification for opioid abuse or dependence, an individual ~~a client~~ who has been previously involved in methadone medication-assisted ~~maintenance~~ treatment may be readmitted without evidence to support findings of current physiological addiction. This can occur if the provider is able to document prior maintenance treatment of six (6) months or more and the physician or their qualified designee, utilizing reasonable clinical judgment, finds readmission to ~~maintenance~~ treatment to be medically justified.

2. Evidence of prior treatment and the criteria used to determine such findings shall be recorded in the clinical ~~client~~ record by the physician or their qualified designee. The physician or their qualified designee shall sign and date the information recorded in the clinical ~~client~~ record. ~~The provider shall not place a client on a maintenance schedule unless the physician has determined that the client is unable to be admitted for services other than maintenance treatment.~~

(f)~~(c)~~ Denying an Individual ~~a Client~~ Treatment.

1. If an individual ~~a client~~ will not benefit from a treatment regimen that includes the use of methadone or other opioid treatment medications ~~medication~~, or if treating the individual ~~client~~ would pose a danger to others ~~other clients staff, or other individuals~~, the individual ~~client~~ may be refused treatment. This is permitted even if the individual ~~client~~ meets the standards for placement. The physician or their qualified designee shall make this determination and shall document the basis for the decision to refuse treatment.

(g)~~(d)~~ Methadone Take-home Privileges.

1. Take-home doses of methadone are permitted only for individuals ~~clients~~ participating in a methadone medication-assisted treatment program ~~on a methadone maintenance regimen~~. Request for take-home doses greater than the amount allowed, as stipulated in subsection (5)(h) of this rule, must be entered into the SAMHSA/CSAT Opioid Treatment Program Extranet for federal and state approval. The following must be indicated on the exception request:

a. Dates of Exception: not to exceed a six (6) month period of time per request.

b. Justification.

c. Dates and results of last three (3) drug screens, for individuals in treatment longer than 90 days.

d. Indication of lock box compliance.

e. Statement of supporting documentation on file.

f. Any other information the provider deems necessary in support of the request.

~~2. Take-home doses of methadone may be granted if the client meets the following conditions:~~

~~a. Absence of recent abuse of drugs as evidenced by drug screening;~~

~~b. Regularity of attendance at the provider;~~

~~c. Absence of serious behavioral problems at the provider;~~

~~d. Absence of recent criminal activity of which the program is aware, including illicit drug sales or possession;~~

~~e. Client's home environment and social relationships are stable;~~

~~f. Length of time in methadone maintenance treatment meets the requirements of paragraph (e);~~

~~g. Assurance that take-home medication can be safely stored within the client's home or will be maintained in a locked box if traveling away from home;~~

~~h. The client has demonstrated satisfactory progress in treatment to warrant decreasing the frequency of attendance; and~~

~~i. The client has a verifiable source of legitimate income.~~

2. The medical director shall make determinations based on take-home criteria as stated in 42 CFR 8.12.

3. When considering an individual's ~~client~~ responsibility in handling methadone, the physician shall consider the recommendations of other staff members who are most familiar with the relevant facts regarding the individual ~~client~~.

4. The requirement of time in treatment and participation is a minimum reference point after which an individual ~~a client~~ may be eligible for take-home privileges. The time in treatment reference is not intended to mean that an individual ~~client~~ in treatment for a particular length of time has a right to take-home methadone. ~~Thus~~ R~~r~~egardless of time in treatment, the physician, state or federal authorities with cause, may deny or rescind the take-home ~~methadone~~ privileges of an individual ~~a client~~.

5. In the event of a disaster that prompts a program-wide exemption authorized by SAMHSA and the SOTA in advance, providers must make appropriate arrangements for unstable individuals. In the event there are medically unstable individuals, providers are responsible for contacting guest dosing centers (i.e. hospitals) in advance to ensure continuity of care. Providers shall make an effort to identify and provide individuals a list of nearby emergency shelters that will allow individuals to bring medication in a locked box.

(h)~~(e)~~ Take-home Phases. To be considered for take-home privileges, all individuals ~~clients~~ shall be in compliance

with criteria as stated in 42 CFR 8.12(h)(2) ~~subparagraph (d)2.~~

1. Differences in the nature of abuse potential in opioid treatment medications determine the course of treatment and subsequent take-home privileges available to the individual based on progress, participation, and circumstances. The assessment and decision approving all take-homes shall be documented in the individual's clinical record, signed and dated by the physician.

2. No take-homes shall be permitted during the first 30 days following placement unless approved by both the state and federal authorities ~~authority~~.

a~~1~~. Phase I. Following 30 consecutive days in treatment, the individual ~~client~~ may be eligible for one (1) take-home per week from day 31 through day 90, provided that the individual ~~client~~ has had negative drug screens and is following program requirements for the preceding 30 days.

b~~2~~. Phase II. Following 90 consecutive days in treatment, the individual ~~client~~ may be eligible for two (2) take-homes per week from day 91 through day 180, provided that the individual ~~client~~ has had negative drug screens for the preceding 60 days.

c~~3~~. Phase III. Following 180 consecutive days in treatment, the individual ~~client~~ may be eligible for three (3) take-homes per week with no more than a two (2)-day supply at any one time from day 181 through one (1) year, provided that the individual ~~client~~ has had negative drug screens for the preceding 90 days.

d~~4~~. Phase IV. Following one (1) year in continuous treatment, the individual ~~client~~ may be eligible for four (4) take-homes per week with no more than a two (2)-day supply at any one time through the second year of treatment, provided that the individual ~~client~~ has had negative drug screens for the preceding 90 days.

e~~5~~. Phase V. Following two (2) years in continuous treatment, the individual ~~client~~ may be eligible for five (5) take-homes per week ~~with no more than a 3-day supply at any one time~~, provided that the individual ~~client~~ has had negative drug screens for the preceding 90 days.

f~~6~~. Phase VI. Following three (3) years in treatment, the individual ~~client~~ may be eligible for six (6) take-homes per week provided that the individual ~~client~~ has passed all negative drug screens for the past year.

3.~~(f)~~ Methadone Medical Maintenance. ~~Providers must receive prior approval in writing from the State Authority to use the medical maintenance protocol. The provider~~ Providers may place an individual ~~a client~~ on methadone medical maintenance in ~~those~~ cases where it can be demonstrated that the potential benefits of medical maintenance to the individual exceed the potential risks, in the professional judgment of the physician. ~~client far exceed the potential~~

~~risks.~~ Only a physician may authorize placement of an individual ~~a client~~ on medical maintenance. The physician shall provide justification in the clinical ~~client~~ record regarding the decision to place an individual ~~a client~~ on medical maintenance.

The following conditions shall apply to medical maintenance.

a~~1~~. To qualify for partial medical maintenance, an individual ~~a client~~ may receive no more than 13 take-homes and must have been in continuous treatment ~~with the same clinic~~ for four years (4) with at least two years (2) of negative drug screens.

b~~2~~. To qualify for full medical maintenance an individual ~~a client~~ may receive no more than 27 take-homes and must have been in continuous treatment ~~with the same clinic~~ for five years (5) with at least three (3) years of negative drug screens.

c~~3~~. All individuals ~~clients~~ in medical maintenance will receive their medication orally in the form of liquid, diskette or tablet. ~~tablet form only~~. Diskettes and tablets are allowed if formulated to reduce potential parenteral abuse.

d~~4~~. All individuals ~~clients~~ will participate in a "call back" program by reporting back to the provider upon notice for a medication count.

e~~5~~. All criteria for take-homes as listed under paragraph (d) shall continue to be met.

~~The provider shall develop operating procedures for medical maintenance.~~

(i)~~(g)~~ Transferred Individuals ~~Transfer Clients~~ and Take-Home Privileges.

1. Any individual ~~client~~ who transfers from one (1) provider to another within the state of Florida shall be eligible for placement on the same phase provided that verification of enrollment and compliance with program requirements is received from the previous provider prior to implementing transfer ~~within two weeks of placement~~. The physician at the previous provider shall also document that the individual ~~client~~ met all criteria for their current phase and are at least on Phase I.

2. Any individual ~~client~~ who transfers from out-of-state is required to comply with the criteria stated in 42 CFR 812(h)(2) ~~meet the requirements of subparagraph (d)2.~~, and with verification of previous clinical ~~client~~ records, the physician shall determine the phase level based on the individual's ~~client's~~ history subject to the approval of state and federal authorities.

(j)~~(h)~~ Transfer Information. When an individual ~~a client~~ transfers from one (1) provider to another, the referring provider shall release the following information:

1. through 5. No change.

6. Documentation of the conditions which precipitated the referral; ~~and~~

7. A written summary of the individual's ~~client's~~ last three (3) months of treatment~~;~~.

8. Any history of behavioral non-compliance, emotional, or legal problems; and

9. A copy of the clinical records to ensure coordination of care, to include: discharge summary, medical assessments, and current medication and dosage. Additional records may be sent based on their appropriateness to ensure coordination of care. This information shall be released prior to the individual's ~~client's~~ arrival at the provider to which he or she is transferred. Providers shall not withhold an individual's ~~a client's~~ records when requested by the individual ~~client~~ for any reason, including failure to pay bills owed to the provider ~~client debt~~. The referring provider shall forward the records directly to the provider of the individual's choosing with signed records releases from the individual ~~client's choice~~.

(k)~~(i)~~ Exemptions from Take-Home Privileges and Phasing Requirements ~~for Methadone Maintained Clients~~.

1. Exemptions for Disability or Illness

a. If an individual ~~a client~~ is found to have a physical disability which interferes with the individual's ~~client's~~ ability to conform to the applicable mandatory schedule, the individual ~~client~~ may be permitted a temporary or permanently reduced schedule by the physician~~,~~ and, at the discretion of the SOTA and federal authorities, provided the individual ~~client~~ is also found to be responsible in handling opioid treatment medication, making progress in treatment, and providing drug screens free of unapproved medications and illicit drugs ~~methadone~~.

b. Providers shall obtain medical records and other relevant information as needed to verify the medical condition ~~physical disability~~. Justification for the reduced attendance schedule shall be documented in the clinical ~~client~~ record by the physician or their qualified designee who shall sign and date these entries.

2. Temporary Reduced Schedule of Attendance

a. An individual ~~A client~~ may be permitted a temporarily reduced schedule of attendance because of exceptional circumstances such as illness, personal or family crises, ~~and~~ travel, or other hardship which causes the individual ~~client~~ to become unable to conform to the applicable mandatory schedule. This is permitted only if the individual ~~client~~ is also found to be responsible in handling opioid treatment medication, has consistently provided drug screens free of

unapproved and illicit drugs, and has made acceptable progress toward treatment goals ~~methadone~~.

b. Any individual using prescription opioid medications or sedative drugs not used in the medication-assisted treatment protocols shall provide a legitimate prescription from the prescribing physician. The physician, or medical designee, shall consult with the prescribing physician to coordinate care as outlined in medical protocols.

c. The necessity for an exemption from a mandatory schedule is to be based on the reasonable clinical judgment of the physician. ~~and~~ Ssuch determination of necessity shall be recorded in the clinical ~~client~~ record by the physician or their qualified designee who shall sign and date these entries. Entries relating to requests for exemptions or exceptions from state or federal requirements shall be reviewed and a decision rendered by state and federal authorities. ~~A client shall not be given more than a 14-day supply of methadone at any one time unless an exemption is granted by the state methadone authority and by the federal government.~~

3. Travel Distance.

a. In those instances where ~~client~~ access to a provider is limited because of travel distance, the physician is authorized to reduce the frequency of an individual's ~~a client's~~ attendance. This is permitted if the individual ~~client~~ is currently employed or attending a regionally approved educational or vocational program or the individual ~~client~~ has regular child-caring responsibilities that preclude daily trips to the provider. This does not extend to individuals who choose to travel further than the closest affordable program to dose.

b. The reason for reducing the frequency of attendance shall be documented in the clinical ~~client~~ record by the physician who shall sign and date these entries. These requests shall be reviewed and rendered a decision by state and federal authorities.

4. Other Travel.

a. Any exemption that is granted to an individual ~~a client~~ regarding travel shall be documented in the clinical ~~client's~~ record. Such documentation shall include tickets prior to a trip, copies of boarding passes, copies of fuel receipts, ~~gas or~~ lodging receipts, or other verification of the individual's ~~client's~~ arrival at the approved destination. If travel is due to medical treatment, documentation shall include a physician's note or related documentation. Generally, special take-homes shall not exceed 27 doses at one (1) time. Request for take-homes in excess of 27 doses must be submitted for approval through SAMHSA/CSAT Opioid Treatment Program Extranet for federal and state approval.

b. Individuals ~~Clients~~ who receive exemptions for travel shall be required to submit to a drug test on the day of

return to the provider ~~facility~~.

(l)~~(j)~~ Random Drug Screening.

1. Individuals in the first six (6) months of treatment shall be required to submit to a~~A~~t least one (1) monthly random drug screen~~, random and monitored, shall be performed on each~~. ~~The drug screen shall be conducted so as to reduce the risk of falsification of results. This shall be accomplished by direct observation or by another accurate method of monitoring.~~

2. Individuals ~~Clients~~ who are on Phase III or higher ~~VI~~ shall be required to submit to a minimum of eight (8) ~~one~~ random drug screens per year ~~screen at least every 90 days~~.

3. All drug screens shall be conducted by direct observation, or by another accurate method of monitoring in order to reduce the risk of falsification of results. ~~Each specimen shall be analyzed for methadone, benzodiazepines, opiates, cocaine, and marijuana.~~

4. The physician shall review all positive drug screens from unapproved medications and illicit drug use in accordance with the medical protocol established in subsection 65D-30.004(7), F.A.C.

(m)~~(k)~~ Employment of Persons on a Maintenance Protocol. No staff member, ~~either~~ full-time, part-time or volunteer, shall be on a maintenance protocol unless a request to maintain or hire staff undergoing treatment is submitted with justification to and approved by the state and federal authorities. Any approved personnel on a maintenance regimen shall not be allowed access to or responsibility for handling methadone or other opioid treatment medication.

(n)~~(1)~~ Caseload. No full-time counselor shall have a caseload that exceeds the equivalent of 32 currently participating clients. Participating individual ~~client~~ equivalents are determined in the following manner.

1. An individual ~~A client~~ seen once per week would count as 1.0 ~~client~~ equivalent.

2. An individual ~~A client~~ seen bi-weekly would count as a .5 ~~client~~ equivalent.

3. An individual ~~A client~~ seen monthly or less would count as a .25 ~~client~~ equivalent.

4. As an example, a counselor has a caseload of 15 individuals ~~clients~~ that are seen weekly (counts as ~~15~~ an equivalent of 15 ~~clients~~), 30 individuals ~~clients~~ seen biweekly (counts as an ~~15~~ equivalent of 15 ~~clients~~), and 8 individuals ~~clients~~ seen monthly (counts as an ~~2~~ equivalent of 2 ~~clients~~). The counselor would have a total caseload of 53 individuals ~~individual clients~~ equaling 32 equivalent individuals ~~clients~~.

(o)~~(m)~~ Termination from Treatment.

1. There will be occasions when individuals ~~clients~~ will need to be terminated from ~~maintenance~~ treatment. Individuals ~~Clients~~ who fall into this category are those who:

a. Attempt to sell or deliver their prescribed medication or any other drugs;~~,~~

b. Become or continue to be actively involved in criminal behavior;~~,~~

c. Consistently fail to adhere to the requirements of the provider;~~,~~

d. Persistently use unapproved medications or illicit drugs other than prescribed treatment medication; ~~methadone,~~ or

e. No change.

Such individuals ~~clients~~ shall be withdrawn in accordance with a dosage reduction schedule prescribed by the physician and referred to other treatment, as clinically indicated. This action shall be documented in the clinical ~~client~~ record by the physician.

2. Providers shall establish criteria for involuntary termination from treatment ~~that describe the rights of clients as well as the responsibilities and rights of the provider~~. All individuals ~~clients~~ shall be given a copy of these criteria upon placement and shall sign and date a statement that they have received the criteria.

(p)~~(n)~~ Withdrawal from Maintenance.

1. The physician shall ensure that all individuals ~~clients~~ in methadone medication-assisted ~~maintenance~~ treatment receive an annual assessment. This assessment may coincide with the annual assessment of the treatment plan and shall include an evaluation of the individual's ~~client's~~ progress in treatment and the justification for continued maintenance. The assessment and recommendations shall be recorded in the clinical ~~client~~ record.

2. All providers shall develop policies and procedures that allow for systemic withdrawal of individuals as part of on-going services of the program. At least annually, the provider shall provide the individual with documentation that explains the titration of medication to maintain therapeutic levels or to withdraw from the medication with the least necessary discomfort. The provider shall discuss the advantages and potential problems associated with withdrawal. The provider shall document the request for titration in the clinical record with course of action and shall be signed by individual and consulting staff.

3. An individual ~~A client~~ being withdrawn from ~~maintenance~~ treatment shall be closely supervised during withdrawal. A dosage reduction schedule shall be established by the physician and documented in the clinical record. In the event withdrawal is clinically inadvisable, justification must be kept in the clinical record, signed and dated by

the physician and individual.

(q)~~(o)~~ Services.

1. Comprehensive Services. A comprehensive range of services shall be available to each individual as required in subsection 397.42791 F.S. ~~client.~~ The type of services to be provided shall be determined by individual ~~client~~ needs, the characteristics of individuals ~~clients~~ served, and the availability of community resources.

2. Counseling.

a. Each individual receiving methadone medication-assisted treatment ~~client on maintenance~~ shall receive regular counseling. A minimum of one (1) counseling session per week shall be provided to individuals ~~new clients~~ through the first 90 days. A minimum of two (2) counseling sessions per month shall be provided to individuals ~~clients~~ who have been in treatment for at least 91 days and up to one (1) year. A minimum of one (1) counseling session per month shall be provided to clients who have been in treatment for longer than one (1) year.

~~b. If fewer sessions are clinically indicated for a client, this shall be justified and documented in the client record. In no case shall sessions be scheduled less frequently than every 90 days. This would apply to those clients who have been with the program longer than three years and have demonstrated the need for less frequent counseling in accordance with documentation in the treatment plan.~~

b~~c~~. A counseling session shall be at least 30 minutes in duration, conducted in a private room, and shall be documented in the clinical ~~client~~ record.

c. Any entity or qualified professional who has entered into a written agreement with a licensed provider is bound by these regulations.

(r) Overdose Prevention

1. All licensed providers must develop overdose prevention plans. Overdose prevention plans must be shared with individuals upon admission and discharge from medication-assisted treatment, regardless of the reason for discharge. Plans must also be shared with individuals placed on a waitlist to receive treatment services. Overdose prevention plans shall include, at a minimum:

a, Education about the risks of overdose, including having a lower tolerance for opioids once the individual is no longer on medication-assisted treatment.

b. Information about Naloxone, the medication that reverses opioid overdose, including where and how to access Naloxone in the county.

c. For providers who maintain an emergency overdose prevention kit, a developed and implemented plan to have staff trained in the prescribed use and the availability of kit for use during all program hours of operation.

(6) Medication Units ~~Satellite Maintenance~~.

(a) A provider that currently holds a state license and who has either exceeded site capacity or has a significant proportion of individuals in treatment with a travel burden, may apply to the SOTA to establish a medication unit. The provider must be in good standing with the Department and applicable regulating agencies. The licensed provider and medication unit must be owned by the same provider. ~~A satellite maintenance dosing station must be operated by a primary, licensed comprehensive maintenance provider and must meet all applicable regulations in Rule 65D-30.004 and subsection 65D-30.014(4), F.A.C.~~

(b) A medication unit's services are limited to medication dosing and drug testing only as outlined in 42 CFR 8.12. ~~In addition to the application for licensure for satellite maintenance, the comprehensive maintenance provider must submit a written protocol containing, at a minimum, a detailed service plan, a staffing pattern, a written agreement with any other organization providing facility or staff, operating procedures, and client eligibility and termination criteria.~~

(c) Providers interested in establishing a medication unit must submit a written proposal to the state authority for review and approval. Proposals that include the following will be approved:

1. Description of proposed medication unit. Include description of target population, geographical catchment area, physical location/address, proposed capacity, and hours of operation;

2. Justification of need for medication unit. Provide explanation on why currently licensed facilities are insufficient and how the proposed medication unit address unmet need;

3. Copy of state license and federal certifications;

4. Information on Medical Director, clinical on-site Director or Manager, and proposed staffing for medication unit;

5. Implementation plan, including timeframes for securing federal approvals for a medication unit and anticipated start date of services;

6. Provide plans to secure proper zoning before medication unit opening; and

7. Describe plan on how medication unit will ensure individuals receive comprehensive support services such as counseling.

(d) Medication units must open within two (2) years of receiving approval.

(7) Best Practices. All licensed providers shall comply with best practices as defined in subsection (4)(e) of this rule.

(8) Buprenorphine Products. Qualified physicians, licensed to practice in the state of Florida and meeting all federal requirements, can prescribe buprenorphine to individuals under their license. Physicians shall conform to federal regulations related to buprenorphine products.

(9) Naltrexone Products. Qualified physicians, licensed to practice in the state of Florida and meeting all federal requirements, shall conform to federal regulations related to naltrexone products.

Rulemaking Authority 397.321(5), ~~397.21(5)~~ FS. Law Implemented 397.311(26), 397.321, 397.410, 397.427, ~~397.311(18)(g), 397.321(1), 397.419, 465~~ FS. History–New 5-25-00, Amended 4-3-03, ____.