

CHAPTER 65D-30
SUBSTANCE ABUSE SERVICES OFFICE

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65D-30.001 Title.

These rules shall be known as the licensure standards for “Substance Abuse Services.”

Rulemaking Authority 397.321(5) FS. Law Implemented 397 FS. History—New 5-25-00, Amended 4-3-03.

65D-30.002 Definitions.

(1) “Abbreviated Treatment Plan” means a shorter version of a treatment plan that is developed immediately following placement in an addictions receiving facility or detoxification component and is designed to expedite planning of services typically provided to individuals placed in those components.

(2) “Accreditation” means the process by which a provider satisfies specific nationally accepted administrative, clinical,

medical, and facility standards applied by an accrediting organization that has been approved by the department.

(3) “Aftercare” means structured services provided to individuals who have completed an episode of treatment in a component and who are in need of continued observation and support to maintain recovery.

(4) “Ancillary Services” as defined in Section 397.311(1), F.S.

(5) “Assessment” means a process used to determine the type and severity of an individual’s substance use problem and includes a psychosocial assessment and, depending upon the component, a physical health assessment.

(6) “Authorized Agent of the Department” as defined in Section 397.311(2), F.S.

(7) “Best Practice” means the combination of specific treatments, related services, organizational and administrative principles, core competencies, or social values designed to most effectively benefit the individuals served. Best Practices also include evidence-based practice, which is subject to scientific evaluation for effectiveness and efficacy. Best Practice standards may be established by entities such as the Substance Abuse and Mental Health Services Administration, national trade associations, accrediting organizations recognized by the Department, or comparable authorities in substance use treatment.

(8) “Business Day” means a day in which the Department’s Office of Substance Abuse and Mental Health is operating for business between 8 a.m. and 5 p.m. (Eastern Standard Time).

(9) “Case Management” means services provided to or on behalf of an individual in order to assess his or her needs, plan or arrange services, coordinate service providers, link the service system to an individual, monitor service delivery, and evaluate the effect of the services received.

(10) “Certification” means a designation earned by an individual or organization demonstrating core competency in a practice area related to substance use prevention, treatment, or recovery support, awarded by a Department-recognized credentialing entity.

(11) “Change in Ownership” means, in addition to Section 397.407(6), F.S.;

(a) An event in which the licensee sells or otherwise transfers its ownership to a different individual or entity as evidenced by a change in federal employer identification number or taxpayer identification number; or

(b) An event in which greater than 50 percent or more of the ownership, shares, membership, or controlling interest of a licensee is in any manner transferred or otherwise assigned. This paragraph does not apply to a licensee that is publicly traded on a recognized stock exchange.

(c) A change solely in the management company or board of directors is not a change of ownership.

(12) “Clinical Record” means all parts of the record required to be maintained that are provided to an individual and includes all clinical records, assessments, financial and legal agreements and consents, progress notes, charts, admission and discharge data, clinical services, clinical summaries, individual therapy notes, group therapy notes, family therapy notes, and other information recorded by the facility staff, which pertains to the individual’s treatment.

(13) “Clinical Services,” for the purposes of this rule chapter, means services such as screening, assessment, level of care determination, treatment planning, and counseling.

(14) “Clinical Staff” means employees of a provider who are responsible for providing clinical services to individuals.

(15) “Clinical Summary,” as used in the context of these rules, means a written statement summarizing the results of the psychosocial assessment relative to the perceived condition of the individual and a further statement of possible service needs based on the individual’s condition.

(16) “Clinical Supervisor” means a person that manages personnel who provide direct clinical services, or a person who maintains lead responsibility for the overall coordination and provision of clinical services. A “Clinical Supervisor” shall meet the qualifications of a “Qualified Professional” as defined in Section 397.311(34), F.S. For the purposes of this rule chapter a Clinical Director is considered a Clinical Supervisor.

(17) “Competency and Ability of Applicant” means a determination that an applicant for a license under Chapter 397, F.S., is able or unable to demonstrate, through a background check on education and employment history, the capability of providing substance abuse services in accordance with applicable laws and regulations.

(18) “Component” or “Service Component” as defined in Section 397.311(42), F.S.

(a) “Addictions Receiving Facility” as defined in Section 397.311(26), F.S.

(b) “Detoxification” as defined in Section 397.311(26), F.S.

(c) “Intensive Inpatient Treatment” as defined in Section 397.311(26), F.S.

(d) “Residential Treatment” as defined in Section 397.311(26), F.S.

(e) “Day or Night Treatment with Community Housing” as defined in Section 397.311(26), F.S.

- (f) “Day or Night Treatment” as defined in Section 397.311(26), F.S.
- (g) “Intensive Outpatient Treatment” as defined in Section 397.311(26), F.S.
- (h) “Outpatient Treatment” as defined in Section 397.311(26), F.S.
- (i) “Aftercare” involves structured services provided to individuals who have completed an episode of treatment in a component and who are in need of continued observation and support to maintain recovery.
- (j) “Intervention” as defined in Section 397.311(26), F.S.
- (k) “Prevention” as defined in Section 397.311(26), F.S.
- (l) “Medication-assisted treatment for opiate addiction” as defined in Section 397.311(26), F.S.
- (19) “Co-occurring Disorder” means a diagnosis of a substance use disorder and a concurrent diagnosis of a mental health disorder.
- (20) “Counseling” means the process, conducted in a facility licensed under Chapter 397, F.S., of engaging an individual and his/her support system (i.e., family, significant other, etc.), as indicated, in a discussion of issues associated with the individual’s substance use and other co-occurring conditions in an effort to work toward a constructive resolution of those problems and ultimately toward recovery. For the purposes of this rule chapter, therapy is considered a type of counseling.
- (21) “Counselor” means a member of the clinical staff, working in a facility licensed under Chapter 397, F.S., whose duties primarily consist of conducting and documenting services such as counseling, psycho-educational groups, psychosocial assessment, and treatment planning.
- (22) “Court Ordered” means the result of an order issued by a court requiring an individual’s participation in a licensed component of a provider under the following authority:
 - (a) Civil involuntary as provided under Sections 397.6811 and 397.693, F.S.;
 - (b) Treatment of individuals with substance use disorders in licensed secure facilities as provided under Section 397.702, F.S.;and
 - (c) Offender referrals as provided under Section 397.705, F.S.
- (23) “Credentialing entity” as defined in Section 397.311(10), F.S.
- (24) “Crisis Intervention” means emergency psychological care aimed at assisting individuals in a crisis situation to restore equilibrium to their biopsychosocial functioning and to minimize the potential for psychological trauma. This includes the methods used to offer immediate, short-term help to individuals who experience an event that produces emotional, mental, physical, and behavioral distress or problems.
- (25) “Designate,” as used in this rule chapter, means the action taken by the Department to approve an Addictions Receiving Facility to provide screening, assessment, evaluation, and treatment to individuals found to be substance use impaired as described in Section 397.675, F.S. and who meet the placement criteria for this component.
- (26) “Detoxification Protocol” means a detailed plan of the medical protocol for the detoxification treatment or procedure. This includes the type of medication, dosage, administration, and components of treatment other than medication.
- (27) “Diagnostic Criteria” means prevailing standards which are used to determine an individual’s mental and physical condition relative to their need for substance use services, such as those which are described in the current Diagnostic and Statistical Manual of Mental Disorders.
- (28) “Diagnostic Services” means services that are provided to individuals who have been assessed as having special needs and that will assist in their recovery such as educational tests, psychometric tests and evaluation, psychological and psychiatric evaluation and testing, and specific medical tests.
- (29) “Direct Care Staff” means employees and volunteers of a provider who provide direct services to individuals.
- (30) “Direct Services” means services that are provided by employees or volunteers who have contact or who interact with individuals receiving services.
- (31) “Discharge Summary” means a written narrative of the individual’s treatment record describing the individual’s accomplishments and challenges during treatment, reasons for discharge, and recommendations for further services.
- (32) “Financial Ability” means a provider’s ability to secure and maintain the necessary financial resources to provide services to individuals in compliance with required standards.
- (33) “Indicated Prevention Services” has the same meaning as provided for the same term in subparagraph 65E-14.021(4)(v)1., F.A.C.
- (34) “Inmate Substance Abuse Programs,” include substance abuse services provided within facilities housing only inmates and

operated by or under contract with the Department of Corrections.

(35) “Initial Treatment Plan” means a preliminary, written plan of goals and objectives intended to inform the individual of service expectations and to prepare the individual for service provision.

(36) “Intervention Plan” means a written plan of goals and objectives to be achieved by an individual who is involved in intervention services.

(37) “Involuntary” means the status ascribed to a person who meets the criteria for admission under Section 397.675, F.S.

(38) “Licensed Bed Capacity” means the total bed capacity of addictions receiving facilities, residential detoxification facilities, and residential facilities.

(39) “Licensing Fee” means revenue collected by the department from a provider required to be licensed under Section 397.407, F.S.

(40) “Medication Administration Record” or “MAR” means the chart maintained for each individual which records the medication information required by this rule chapter. Other information or documents pertinent to medication administration may be attached to the MAR.

(41) “Medical Consultant” means a physician licensed under Chapter 458 or 459, F.S., who has an agreement with a licensed provider to be available to consult on any services required by individuals involved in those licensed components.

(42) “Medical Director” means a physician licensed under Chapter 458 or 459, F.S., who has been designated to oversee all medical services of a provider and has been given the authority and responsibility for medical care delivered by a provider.

(43) “Medical History” means information on the individual’s past and present general physical health, including the effect of substance use on the individual’s health.

(44) “Medical Maintenance” means special clinical protocols that permit extending the amount of consecutive take-home methadone provided to individuals who are involved in medication-assisted treatment for opioid addiction and who qualify through a special exemption from the Department for participation under these protocols. Medical maintenance may be either partial (13 consecutive take-home doses) or full (27 consecutive take-home doses).

(45) “Medication Administration Record” or “MAR” means the chart maintained for each individual which records the medication administered to an individual as required by this rule chapter. Other information or documents pertinent to medication administration may be attached to the MAR.

(46) “Medication Observation Record” or “MOR” means the chart maintained for each individual which records medication that is self-administered by an individual.

(47) “Medication Error” means medication that is administered or dispensed to an individual in a dose that is higher or lower, with greater or lesser frequency, or that is the wrong medication than that which is prescribed under a physician’s order.

(48) “Methadone Medication-Assisted Treatment Sponsor” means a representative of a methadone medication-assisted treatment provider who is responsible for its operation and who assumes responsibility for all its employees and volunteers, including all practitioners, agents, or other persons providing services at the provider.

(49) “Nursing Physical Screen” means a procedure for taking an individual’s medical history and vital signs and recording any general impressions of an individual’s current physical condition, general body functions, and current medical problems.

(50) “Nursing Support Staff” means persons who assist Registered Nurses and Licensed Practical Nurses in carrying out their duties, but who are not licensed nurses.

(51) “Operating Procedures” means written policies and procedures governing the organization and operation of a provider that include methods of implementation and accountability.

(52) “Organizational Capability” means a provider’s ability to implement written operating procedures in conformance with required standards.

(53) “Overlay” means a component operated within facilities not owned or operated by a provider.

(54) “Owner” means the owner of record of a licensed facility that has an enforceable claim or title to an asset or property and is recognized as such by law.

(55) “Physical Examination” means a medical evaluation of the individual’s current physical condition.

(56) “Physical Health Assessment” means a series of services that are provided to evaluate an individual’s medical history and present physical condition and include a medical history, a nursing physical screen, a physical examination, laboratory tests, tests for contagious diseases, and other related diagnostic tests.

(57) “Placement” means the process used to determine individual admission to, continued stay in, and transfer or discharge from

a component in accordance with specific criteria.

(58) "Prevention Plan" means a plan of goals to be achieved by an individual or family involved in structured indicated prevention activities on a regularly scheduled basis.

(59) "Primary Counselor" means the provider's staff who has primary responsibility for delivering and coordinating clinical services for specific individuals in treatment.

(60) "Private Practice," as used in these rules, means a sole proprietorship, an individual or individuals using shared office space, or other business entity, required to be licensed under Chapter 397, F.S.

(61) "Privately Funded Provider" means a provider which relies solely on private funding sources.

(62) "Program Office" means the specific office of the Department identified as the single state authority for substance abuse.

(63) "Progress Notes" means written entries made in the clinical record that specify the intervention provided, and document progress or lack thereof toward meeting treatment plan objectives, and which generally address the provision of services, the individual's response to those services, and significant events.

(64) "Protective Factors" means those conditions that inhibit, reduce, or protect against the probability of the occurrence of drug use or abuse.

(65) "Provider" or "Service Provider" means a public agency, a private for-profit or not-for-profit agency, a person who is in private practice, and a hospital, licensed under Chapter 397, F.S., or exempt from licensure.

(66) "Psychosocial Assessment" means a series of evaluative measures designed to identify the behavioral and social factors involved in substance abuse and its symptoms, and is used in the determination of placement and the development of the treatment plan.

(67) "Publicly Funded Provider" means a provider that receives funds directly from the department, Medicaid, or another public agency or is a state agency or local government agency.

(68) "Qualified Professional" as defined in Section 397.311(34), F.S.

(69) "Quality Assurance" means a formal method of evaluating the quality of care rendered by a provider and is used to promote and maintain an efficient and effective service delivery system. Quality assurance includes the use of a quality improvement process to prevent problems from occurring so that corrective efforts are not required.

(70) "Regional Substance Abuse and Mental Health Office" or "Regional Office" means a local Substance Abuse and Mental Health Program office of the Department.

(71) "Resident" means an individual receiving treatment for a substance use disorder or co-occurring substance use and mental health disorders within a structured, non-hospital, live-in environment.

(72) "Restraint" as defined in Section 394.455(41), F.S.

(73) "Risk Factors" means those conditions affecting a group, individual, or defined geographic area that increase the likelihood of a substance use or substance abuse problem.

(74) "Seclusion" as defined in Section 394.455(42), F.S.

(75) "Selective Prevention Services" has the same meaning as provided for the same term in subparagraph 65E-14.021(4)(w)1., F.A.C.

(76) "Services" means assistance that is provided to individuals and their support system (i.e., family, significant other, etc.), as indicated, in their efforts to reduce or eliminate substance use free, such as counseling, treatment planning, vocational activities, educational training, and recreational activities.

(77) "Stabilization" as defined in Section 397.311(45) F.S.

(78) "Substantial Compliance" means an applicant for a new license that is in the initial stages of developing services, has demonstrated the ability to implement the requirements of these rules through operating procedures, and is thereby eligible for a probationary license.

(79) "Substantial Noncompliance" means that a provider operating on a regular license has significant violations, or a pattern of violations, which affects the health, safety, or welfare of individuals and, because of those violations, is issued an interim license or is subject to other sanctions as provided for in Section 397.415, F.S.

(80) "Summary Note" means a written record of the progress made by individuals involved in intervention services and indicated prevention services.

(81) "Supportive Counseling" means a form of counseling that is primarily intended to provide information and motivation to individuals.

(82) “Telehealth” means the mode of providing care, treatment, or services by a Florida qualified professional, as defined under Section 397.311(34), F.S., within the scope of his or her practice, through the use of clinical and medical information exchanged from one site to another via electronic communication. Telehealth does not include the provision of health services only through an audio only telephone, email messages, text messages, facsimile transmission, U.S. mail or other parcel service, or any combination thereof.

(83) “Transfer Summary” means a written justification of the circumstances of the transfer of an individual from one (1) component to another or from one (1) provider to another.

(84) “Treatment” or “Clinical Treatment” as defined in Section 397.311(26)(a), F.S.

(85) “Treatment Plan” as defined in Section 397.311(49), F.S.

(86) “Universal Direct Prevention Services” has the same meaning as provided for the same term in subparagraph 65E-14.021(4)(x)1., F.A.C.

(87) “Universal Indirect Prevention Services” has the same meaning as provided for the same term in subparagraph 65E-14.021(4)(y)1., F.A.C.

(88) “Verbal De-escalation” means approved non-physical techniques and procedures used to manage a potentially aggressive situation and prevent it from escalating into physical aggression.

(89) “Written Communication” or “In Writing” means a form of either electronic or postal communication.

Rulemaking Authority 397.321(5) FS. Law Implemented 397.311, 397.321(1), 397.410 FS. History—New 5-25-00, Amended 4-3-03, 12-12-05, 8-29-19.

65D-30.003 Department Licensing and Regulatory Standards.

(1) Licensing.

(a) License Required. All substance use abuse components, as defined in subsection 65D-30.002(17), F.A.C., must be provided by persons or entities that are licensed by the Department pursuant to Section 397.401, F.S., unless otherwise exempt from licensing under Section 397.4012, F.S., prior to initiating the provision of services.

(b) Licenses Issued by Component. The Department shall electronically issue one license for each service component offered by a provider. A separate license is not required for the same component. A license is valid only for the specific service component listed for each specific location identified on the license. Each location listed on the license shall reflect the license type for that component. The provider shall print the most recent version of the license and display a copy in each facility providing the licensed service component. One (1) license is required where all facilities are maintained on the same premises and operated under the same management. If there are multiple buildings on the same premises, the buildings must appear as part of one (1) entity. For the purposes of paragraph (b), living arrangements utilized for individuals of day or night treatment with community housing do not constitute facilities or separate premises.

(2) Mandatory Accreditation.

(a) In accordance with Section 397.403(3), F.S., providers shall achieve accreditation by an accrediting organization recognized by the Department, as discussed in Rule 65D-30.0031, F.A.C. Accreditation is required for all clinical treatment services and for each location services are offered. Accreditation cannot be attained without a Department issued license for substance abuse treatment services.

(b) Applicants for licensure and licensed service providers must meet current best practice standards related to the licensable service components of the accrediting organization. When a provider who has attained accreditation is in noncompliance with accrediting standards, the provider must notify the Department within 10 days. A copy of the Quality Assurance plan and proof of corrected areas must be submitted to the Department upon request.

Rulemaking Authority 397.321(5) FS. Law Implemented 397.321(6), 397.403, 397.410 FS. History—New 5-25-00, Amended 4-3-03, 12-12-05, 8-29-19.

65D-30.0031 Certifications and Recognitions Required by Statute.

(1) Department Recognition of Accrediting Organizations.

(a) The Department shall recognize one (1) or more professional credentialing entities as an accrediting organization for persons providing substance use treatment, prevention, and recovery support services. A list of Department recognized accrediting organizations can be found at the following link: <http://www.myflfamilies.com/service-programs/substance-abuse>.

(b) Accrediting organizations that desire Department recognition shall submit a request in writing to the Director for the Office of Substance Abuse and Mental Health. The Director for the Office of Substance Abuse and Mental Health shall respond in writing to the organization's chief executive officer denying or granting recognition. An organization must meet the following criteria in order to be granted recognition by the Department.

1. The accrediting organization shall have fees and practice standards which apply to substance use services. These standards shall incorporate administrative, clinical, medical, support, and environmental management standards.

2. The accrediting organization shall have written procedures detailing the survey and accreditation process.

3. The accrediting organization shall submit evidence of three (3) years of experience functioning as an accreditation organization for substance use services.

4. For the purposes of this rule, a service provider must hold a valid license for each service component type prior to seeking accreditation for substance use treatment services, as defined in subsection 65D-30.002(17), F.A.C.

5. The provider must submit the accrediting survey report to the Department.

(2) Department Recognition of Credentialing Entities.

(a) The Department shall recognize one (1) or more professional credentialing entities as a certifying organization for addiction professionals. A list of Department recognized credentialing organizations can be found at the following link: <http://www.myflfamilies.com/service-programs/substance-abuse/licensure-regulation>. An organization that desires recognition by the Department as a certifying organization for addiction professionals shall request such approval in writing from the Department. Organizations seeking approval shall be:

1. A non-profit and governed by a Board of Directors representative of the population it intends to certify;

2. Include specific requirements which applicants must meet to become certified and to maintain certification;

3. Establish core competencies, certification standards, and examination instruments according to nationally recognized certification and psychometric standards;

4. Require annual continuing education units to ensure addiction treatment, prevention, or recovery support subject matter content is current;

5. Require applicants and certificants to adhere to a professional code of ethics and disciplinary process;

6. Conduct investigations into allegations of professional misconduct; and

7. Maintain a web-based public-access database of certificants' status, including ethical violation history.

(b) The Department shall recognize one (1) or more credentialing entities as a certifying organization for recovery residences who meets all requirements of Section 397.487, F.S. A list of Department recognized credentialing entities can be found at the following link: <http://www.myflfamilies.com/service-programs/samh/recovery-residence>. An organization that desires recognition by the Department as a certifying organization for recovery residences shall request such approval in writing from the Department.

Rulemaking Authority 397.321(5) FS. Law Implemented 397.321(6), (15), 397.403, 397.4871 FS. History—New 8-29-19.

65D-30.0032 Display of Licenses.

(1) Display of Licenses. Licenses shall be displayed in a conspicuous, publicly accessible place within each facility.

(2) A license is valid only for the provider, location(s), service component, and type for which the license is issued.

(3) Licenses shall exhibit the name under which the provider conducts business.

(4) Marketing or advertising materials shall use the legal entity's name registered with the Division of Corporations, and any reference to a service component must use the name of the licensed service component as defined in Section 397.311(26), F.S. and subsection 65D-30.002(17), F.A.C.

(5) Special Information Displayed on Licenses. In the case of addictions receiving facilities, inpatient detoxification, intensive inpatient treatment, and residential treatment, each license shall include the licensed bed capacity. The Department shall identify on the license all component(s) accredited by an accrediting organization recognized by the Department, which may be found at the following link: <http://www.myflfamilies.com/service-programs/substance-abuse/licensure-regulation>. In the case of providers or components of providers that are accredited, licenses shall also include the following statement, "THIS LICENSE WAS ISSUED BASED, IN PART, ON THE SURVEY REPORT OF A DEPARTMENT RECOGNIZED ACCREDITING ORGANIZATION." This statement will not be included on the license when issuance is also based on the results of the Department's licensing inspections.

(6) All licenses, certifications, or recognitions of any entity pursuant to this chapter shall also include the following statement,

“The issuance of a license, certification, or recognition pursuant to Chapter 65D-30, F.A.C., neither guarantees, expresses, nor implies an outcome. A license, certification, or recognition represents attainment of the minimum standards to conduct business as a substance use disorder treatment or prevention provider in the state of Florida.”

(7) Failure to properly display a license is a Class IV violation as defined in Rule 65D-30.0038, F.A.C., and must be corrected within five (5) calendar days.

Rulemaking Authority 397.321(5) FS. Law Implemented 397.321(6), 397.407, 397.410 FS. History—New 8-29-19.

65D-30.0033 License Types.

(1) Probationary License.

(a) Conditions Permitting Issuance. A probationary license is issued to a new applicant upon completion of all applicable requirements. For providers licensed for the same component at multiple locations, the license will display which service component locations are probationary and which provider locations have a current regular license for that service component.

(b) If all licensure requirements are not met after issuing of a probationary license, a regular license will not be issued. If the applicant continues to pursue licensure, a new application including the applicable fees must be submitted.

(c) Special Requirements Regarding Probationary Licenses. The following special requirements apply regarding new applicants:

1. A new applicant shall refrain from providing non-exempt services until a probationary license is issued;
2. New applicants that lease or purchase any real property during the application process do so at their own risk. Such lease or purchase does not obligate the Department to approve the applicant for licensing; and
3. In instances where an applicant fails to admit individuals for services during the initial probationary period, the Department shall not issue a regular license, even where other standards have been met. If an applicant continues to pursue licensure, the applicant must reapply and pay the associated fees.
4. The Department shall not issue a probationary license when doing so would place the health, safety, or welfare of individuals at risk.

(d) Issuing New Licenses. All licenses issued to a provider shall have the same expiration dates; any additional licenses that are issued to the provider will carry the same expiration date as provider’s existing regular licenses.

(2) Regular License.

(a) A regular license is valid for a period of 12 months from the date of issuance.

(b) If a regular license replaces a probationary license, the regular license shall be valid for a period of 12 months from the date the probationary license was issued if there are no other licenses issued to the provider.

(c) When a provider has an existing regular license, the regular license replacing a probationary license will carry the same expiration date as the provider’s existing license.

(d) When a regular license replaces an interim license, the anniversary date of the regular license shall not change.

(3) Interim License.

(a) Conditions Permitting Issuance. An interim license will replace a regular license for a period not to exceed 90 days, where the Department finds that any one (1) of the following conditions exist.

1. A facility or component of the provider is in substantial noncompliance with licensing standards. A provider is considered in substantial noncompliance if it is in compliance with less than 80 percent of the licensing standards.
2. The provider has failed to provide proof of compliance with local fire, safety, or health requirements.
3. The provider is involved in license suspension or revocation proceedings.

All components within a facility that are affected shall be listed on the interim license.

(b) Reissuing an Interim License. The Department may reissue an interim license for an additional 90 days at the end of the initial 90-day period in the case of extreme hardship. Extreme hardship is defined as an inability to reach full compliance that cannot be attributed to the provider.

Rulemaking Authority 397.321(5) FS. Law Implemented 397.321(6), 397.407, 397.410 FS. History—New 8-29-19.

65D-30.0034 Change in Status of License.

(1) Changing the Status of Licenses. Changes to a provider’s license shall be permitted under the following circumstances:

(a) If adding a new site to an existing licensed component, the Department will issue a license which shall indicate a probationary license type for the specific location. Once the provider has satisfied the requirements for a regular license, the

Department shall reissue an amended license to reflect the license type as regular. The provider will print the most recent version of the license and display it in a conspicuous, publicly accessible place within each facility;

(b) If a component operating under a regular license is found to be in substantial noncompliance, the Department will amend the license to reflect an interim type at that site. Once the provider has satisfied the requirements of a regular license for that component at the specific site, the Department will reissue a license to reflect a regular license type for that location. For each time the license is issued or reissued by the Department, the provider will print the most recent version of the license and display it in a conspicuous place, publicly accessible within each facility;

(c) A provider's current license shall be amended when a component at a specific site is discontinued. In such cases, the provider shall destroy its current license only after receipt of an amended license. Locations not affected by this provision shall be permitted to continue operation;

(d) Whenever there is a change in a provider's licensed bed capacity equal to or greater than 10 percent, the provider shall notify the Department within 24 hours of the change. The Department shall issue an amended license to the provider within 30 business days of receipt of notice;

(e) When there is a change in a provider's status regarding accreditation, the provider shall notify the Department in writing within five (5) business days of such change. In instances, where the change in status will adversely affect the provider's license or requires other sanctions, the Department shall notify the provider within 30 business days of receipt of the notice of the Department's pending action; and

(f) Any change in the name of a facility that remains under the same ownership and management shall be submitted in writing to the regional office within 30 days prior to the effective date of the change. Upon receipt of the notification, the regional office will issue a letter confirming receipt of the notification along with a replacement license listing the correct facility name. Following failure to provide such notification to the regional office, the Department shall issue the administrative penalty as established in subsection 65D-30.0038(6), F.A.C.

(2) License Non-transferable. In addition to Section 397.407(6), F.S., an acquisition of a majority of ownership shall require the submission of a new application for each component affected. A change in ownership of less than a majority of the ownership interest in a licensed entity only requires submittal of a local and Level 2 background check. All owners shall be screened according to the level 2 screening requirements of Chapter 435, F.S.

(a) Licenses are not transferable:

1. Where an individual, a legal entity or an organizational entity, acquires an already licensed provider or site as described herein; or

2. Where a provider relocates or a component of a provider is relocated or the address where services are rendered changes.

(b) Submitting Applications. A completed "Application for Licensure to Provide Substance Use Services," CF-MH Form 4024, July 2019, incorporated by reference and available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-10903>, shall be submitted to the Department at least 30 days prior to acquisition or relocation. In lieu of the paper "Application for Licensure to Provide Substance Use Services," the applicant may complete an on-line process through the Department's statewide electronic system specific to licensure, which can be accessed at <http://www.myflfamilies.com/service-programs/substance-abuse/licensure-regulation>. The online application, CF-MH Form 4024a, July 2019, is incorporated by reference and available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-10902>. The "Treatment Resource Attestation," CF-MH 4055, July 2019, which is referenced in form CF-MH 4024, is incorporated by reference and available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-10905>.

1. Acquisition. An entity shall submit an Application for Licensing to Provide Substance Abuse Treatment Services to the Department 30 days prior to a change in controlling ownership as defined in this rule of the licensed provider or of the contractual management entity. Failure to register the provider and submit an application 30 days prior to a change will result in the invalidation of the provider's license or site, provided that the change in ownership occurs, effective the date of the action changing the control of ownership or management. In addition to the application, online application or C&F-SA Form 4024, Nov 2017, the applicant shall be required to submit all items as required in subsection 65D-30.0036(1), F.A.C. When the application is considered complete, the Department shall issue a probationary license.

2. Relocation. In addition to an Application for Licensing to Provide Substance Abuse Treatment Services, if there is no change in the provider's services, the provider shall only be required to provide proof of general liability insurance coverage and compliance with local fire and safety standards established by the State Fire Marshal, health codes, appropriate zoning, and occupational

license/business tax receipt. If there is a change in the provider’s services, the provider shall be required to submit all items as required in subsection 65D-30.0036(1), F.A.C. In this latter case, when the Department determines the application to be complete, the Department shall issue a probationary license. A regular license will not be issued if relocating during a probationary period, and the applicant must re-apply.

3. Temporary Relocation. A provider may temporarily relocate services when an evacuation is necessary in order to protect the health, safety, and welfare of individual’s being served.

a. Information on the emergency circumstances requiring temporary relocation of services and options to transfer individuals to another provider shall be made available to individuals in treatment, prior to any emergency action taken by the provider, and acknowledgement of the information shall be documented in the clinical record. The provider shall discharge individuals who can be safely discharged.

b. The provider must notify the Regional Substance Abuse and Mental Health Office by phone or electronic mail within five (5) business days of relocation.

c. If the temporary relocation exceeds 30 business days, prior approval is required by the Regional Substance Abuse and Mental Health Program Office. The provider shall submit a written request to the Department, including justification for the temporary relocation, the beginning and ending dates of the temporary relocation, and a plan for the transfer of any individuals to other providers. The regional office shall approve written requests containing the required information. The regional office shall send a written approval or denial to the provider.

d. During temporary relocation, a provider must deliver or arrange for appropriate care and services to all individuals.

Rulemaking Authority 397.321(5) FS. Law Implemented 397.321(6), 397.403, 397.407, 397.410 FS. History—New 8-29-19.

65D-30.0035 Required Fees.

(1) Licensing Fees. Applicants for a license to operate a licensed service component shall be required to pay a fee upon submitting an application to the regional office. The fees paid by privately-funded providers shall exceed fees paid by publicly-funded providers, as required in Section 397.407(1), F.S. Applicants shall be allowed a reduction, hereafter referred to as a discount, in the amount of fees owed the Department. The discount shall be based on the number of facilities operated by a provider. The fee schedules are listed by component as follows:

Publicly-Funded Providers	
Service Component	Fee (\$)
Addictions Receiving Facility	325
Detoxification	325
Intensive Inpatient Treatment	325
Residential Treatment	300
Day or Night Treatment with Community Housing	250
Day or Night Treatment	250
Intensive Outpatient Treatment	250
Outpatient Treatment	250
Methadone Medication-Assisted Treatment for Opioid Addiction	350
Aftercare	200
Intervention	200
Prevention	200
Applications to provide overlay services should be accompanied by the fee equal to the amount of the licensure fee for the relative service component(s).	
Relocation Fee – The relocation fee is based on the fee charged for the component(s) being relocated. The relocation fee will be waived if due to a natural disaster.	

Schedule of Discounts	
Number of Licensed Facilities	Discount

2-5	10%
6-10	15%
11-15	20%
16-20	25%
20+	30%
Privately-Funded Providers	
Service Component	Fee (\$)
Addictions Receiving Facility	375
Detoxification	375
Intensive Inpatient Treatment	350
Residential Treatment	350
Day or Night Treatment with Community Housing	300
Day or Night Treatment	300
Intensive Outpatient Treatment	300
Outpatient Treatment	300
Methadone Medication-Assisted Treatment for Opioid Addiction	400
Aftercare	250
Intervention	250
Prevention	250
Applications to provide overlay services should be accompanied by the fee equal to the amount of the licensure fee for the relative service component(s).	
Relocation Fee – The relocation fee is based on the fee charged for the component(s) being relocated. The relocation fee will be waived if due to a natural disaster.	

Schedule of Discounts	
Number of Licensed Facilities	Discount
2-5	5%
6-10	10%
11-15	15%
16-20	20%
20+	25%

(2) The licensure fee must be included with all applications. Applications will not be processed if the fee is not received within 30 business days of the submission of the application.

Rulemaking Authority 397.321(5) FS. Law Implemented 397.321(6), 397.407 FS. History—New 8-29-19.

65D-30.0036 Licensure Application and Renewal.

(1) Application for Licensing. Applications for licensing shall be submitted initially and annually thereafter to the Department along with the required licensing fee. An application for renewal of a regular license must be submitted to the Department at least 60 business days prior to the expiration of the regular license. Applications for renewal submitted less than 60 business days, but at least 30 business days before the license expires, will be processed and late fees will be applied. If the application for renewal is not received by the Department 30 business days prior to the expiration of the regular license, the application will be denied and returned to the applicant, including any fees. In addition to requirements pursuant to Section 397.403, F.S., and unless otherwise specified, all applications for licensure shall include the following:

(a) A standard application for licensing, using CF-MH Form 4024, Feb 2018, titled “Application for Licensing to Provide Substance Abuse Treatment Services,” incorporated herein by reference in Rule 65D-30.0034, F.A.C. In lieu of a standard application, the applicant may complete an on-line process through the Department’s statewide electronic system specific to licensure, which can be accessed at <http://www.myflfamilies.com/service-programs/substance-abuse/licensure-regulation>;

(b) Written proof of compliance for all licensed facilities, including community housing, with local health, fire and safety inspections;

(c) A copy of the provider's valid occupational license/business tax receipt, and zoning. (Inmate Substance Abuse Programs operated by or under contract with the Department of Corrections or the Department of Management Services are exempt from this requirement);

(d) A copy of the individual service fee schedule and policy regarding an individual's financial responsibility. (Inmate Substance Abuse Programs operated by or under contract with the Department of Corrections or the Department of Management Services are exempt from this requirement);

(e) A comprehensive outline of the services to be provided, including the licensed bed capacity for addictions receiving facilities, inpatient detoxification, intensive inpatient treatment, residential treatment, and day or night treatment with community housing. The outline must be submitted with the initial application, with the addition of each new service component, or when there is a change of ownership, and it must provide sufficient detail to ensure consistency with clinical best practices;

(f) Information that establishes the name and address of the applicant, its chief executive officer, the chief financial officer, clinical supervisor and, if a corporation or legal entity, the name of each member of the applicant's board, the name of the owner, the names of any officers of the corporation, and the names of any shareholders or persons who hold an equitable interest;

(g) Information on the competency and ability of the applicant, chief executive officer, chief financial officers, and clinical supervisors to carry out the requirements of these rules, including education, previous employment history, and list of references. (Inmate Substance Abuse Programs operated by or under contract with the Department of Corrections, or the Department of Management Services are exempt from this requirement);

(h) Proof of the applicant's financial ability and organizational capability to operate in accordance with these rules, such as a financial audit or review conducted by a certified accountant within the last 12 months of the calendar year. The fiscal infrastructure should demonstrate an understanding of generally accepted accounting principles to ensure program stability. (Providers that are accredited by a Department recognized accrediting organizations and Inmate Substance Abuse Programs operated by or under contract with the Department of Corrections or the Department of Management Services are exempt from this requirement);

(i) Proof of professional liability and general liability coverage. (Inmate Substance Abuse Programs operated by or under contract with the Department of Corrections or the Department of Management Services are exempt from this requirement) Professional liability insurance coverage shall be in an amount not less than \$250,000 per claim, with a minimum annual aggregate of not less than \$750,000;

(j) Confirmation of completion of basic HIV/AIDS education requirements pursuant to Section 381.0035, F.S., for renewal applications;

(k) A current organizational chart;

(l) Demonstration of organizational capability through a written, indexed system of policies and procedures that are descriptive of services and the population served. If delivering services through telehealth, detailed procedures outlining the equipment and implementation plan for services shall be included. Providers utilizing telehealth must implement technical written policies and procedures for telehealth systems that comply with the Health Insurance Portability and Accountability Act privacy regulations, as well as applicable state and federal laws that pertain to patient privacy. Policies and procedures must also address the technical safeguards required by Title 45, Code of Federal Regulations, section 164.312, where applicable. All staff shall have a working knowledge of the substance use operating procedures;

(m) Verification that a qualified professional(s) is included on staff;

(n) Proof of a valid medical license for the medical director. The medical license must be free of administrative action(s), and be accompanied by the following documentation:

1. A copy of photo identification matching that of the physician named on the medical license; and

2. A letter from the physician attesting that he or she is:

a. Employed or contracted by the provider as a medical director, and specifying in which component he or she is acting (addictions receiving facility, detoxification, intensive inpatient treatment, residential treatment, or methadone medication-assisted treatment); and

b. Knowledgeable of the limitations to acting as medical director;

(o) The Drug Enforcement Administration registration for all physicians;

(p) A state of Florida pharmacy permit for methadone medication-assisted treatment for opioid addiction and detoxification and

any applicant with a pharmacy;

(q) Verification of the services of a consultant pharmacist for addictions receiving facility, detoxification, intensive inpatient, residential and methadone medication-assisted treatment for opioid addiction;

(r) Verification of professional licenses issued by the Department of Health;

(s) Verification that fingerprinting and background checks, including local law enforcement checks, have been completed as required by Chapters 397 and 435, F.S.;

(t) Proof of the availability and provision of meals for addictions receiving facilities, inpatient detoxification, intensive inpatient treatment, residential treatment, day or night treatment with community housing, and day or night treatment, if applicable in the case of the two (2) latter components. (Inmate Substance Abuse Programs operated by or under contract with the Department of Corrections or the Department of Management Services are exempt from this requirement);

(u) Proof of accreditation or application for accreditation by a Department recognized accrediting organization for each location and clinical service component offered.

(2) Items listed in paragraphs (1)(a)-(n) must accompany the application for a license and shall be maintained. Renewal applicants shall submit item (1)(u) along with the licensure application. However, regarding items in paragraph (1)(g), only new applicants or where there is a change in chief executive officer, chief financial officers, or clinical supervisors shall submit this information with the application. Items listed in paragraphs (1)(o)-(t), including items in paragraph (1)(l) for renewal applicants, shall be made available for review at the provider facility. In addition, documents listed in paragraphs (1)(a)-(u) that expire during the period the license is in effect shall be renewed by the provider prior to expiration. The Department shall be notified by the provider in writing within 24 hours upon renewal or in the event renewal does not occur. Accreditation is required for all clinical treatment components. Applications for licensure renewal shall submit proof of application for accreditation by a Department approved accrediting entity and proof of obtained accreditation for any subsequent renewals.

(3) In addition to the requirements outlined in paragraphs (1)(a)-(u) of this rule, methadone medication-assisted treatment for opioid addiction providers must submit the following:

(a) Verification of certification from the Substance Abuse and Mental Health Administration relating to methadone medication-assisted treatment for opioid addiction, submitted with the initial application and documented approval from the Substance Abuse and Mental Health Administration, and where there is a change in the owner of record, sponsor, or physician; and

(b) The Drug Enforcement Administration registration for methadone medication-assisted maintenance treatment for opioid addiction.

(4) In addition to the requirements outlined in paragraphs (1)(a)-(v) of this rule, day or night treatment with community housing providers shall submit information regarding location and the number of beds available in community housing with the application for licensure.

(5) An applicant, provider, or legal entity is required to register or file with the Florida Secretary of State, Division of Corporations. The principal name and mailing addresses submitted with the licensure application for the applicant, provider or controlling interests must be the same as the information registered with the Division of Corporations. (Inmate Substance Abuse Programs operated by or under contract with the Department of Corrections, or the Department of Management Services are exempt from this requirement).

(6) Nonresponsive applicant. If certified mail sent to the provider's address of record, mailing address if applicable, is returned as unclaimed or undeliverable, the Department will send a copy of the letter by regular mail to the provider's address of record, or mailing address if applicable, with a copy to the applicant's address if different from the provider. The applicant must respond to the request within 21 days of the date of the letter sent by regular mail. If timely response is not received, the application will be denied.

(7) Accredited Providers. This subsection implements Sections 397.403 and 394.741(4), F.S. and applies to licensing inspections of providers or components of providers that are accredited by Department approved accrediting organizations. A list of Department approved accrediting agencies may be obtained from the Department of Children and Families, Office of Substance Abuse and Mental Health: <http://www.myflfamilies.com/service-programs/substance-abuse/licensure-regulation>. For accredited providers or components of providers, the Department shall conduct a licensing inspection once every three (3) years.

(a) Inspections of Accredited Providers. In addition to conducting licensing inspections every three (3) years, the Department has the right to conduct inspections of accredited providers in accordance with Section 394.741(6) and 397.411, F.S., in cases where any of the following conditions exist:

1. The accredited provider or component of the provider fails to submit the accreditation report and any corrective action plan

related to its accreditation upon request by the Department;

2. The provider or component of the provider has not received or has not maintained accreditation as provided for in paragraph (7)(b) of this rule;

3. The Department's investigation of complaints results in findings of one (1) or more violations of the licensing standards of any accredited component; or

4. The Department has concerns regarding the health, safety or welfare of individuals served.

(b) Determination of Accreditation. Providers shall submit a copy of the accreditation survey report to the Department annually. The Department shall review the report and confirm that accreditation has been awarded for the applicable components. If the survey report indicates that the provider or any components of the provider have been issued provisional or conditional accreditation, the Department shall conduct a licensing inspection as permitted in paragraph (7)(a) of this rule.

Rulemaking Authority 394.46715, 394.879, 397.321(5) FS. Law Implemented 397.321(6), 397.4014, 397.403, 397.407, 397.410, 397.411 FS. History—New 8-29-19.

65D-30.0037 Department Licensing Procedures.

(1) Department Licensing Procedures. The regional offices shall be responsible for licensing providers operating within their geographic boundaries but are not prohibited from reviewing applications or conducting audits of service providers outside the boundary.

(a) Application Process. The regional offices shall process all new and renewal applications for licensing and shall notify both new and renewal applicants in writing within 30 business days of receipt of the application that it is complete or incomplete. Where an application is incomplete, the regional office shall specify in writing to the applicant the items that are needed to complete the application. Following receipt of the regional office's response, the applicant shall have 10 business days to submit the required information to the regional office. If the applicant needs additional time to submit the required information, it may request such additional time within five (5) business days of the deadline for submitting the information. Within five (5) business days of receipt of the request, the regional office shall approve the request for up to an additional 30 business days. Any renewal applicant that fails to meet these deadlines shall be assessed an additional fee equal to the late fee provided for in Section 397.407(3), F.S., \$100 per licensed component for each specific location. If the applicant is seeking a new license and fails to meet these deadlines, the application and all fees shall be returned to the applicant unprocessed.

(b) Licensing Inspection. The regional office may conduct announced or unannounced on-site licensing inspections pursuant to Section 397.411, F.S. Prior to any scheduled inspection, the regional office shall notify the applicant of its intent to conduct an on-site licensing inspection or electronic file review and of the proposed date of the inspection. The regional office shall include the name(s) of the authorized agents who will conduct the inspection and the specific components and facilities to be inspected. This notification, however, shall not prohibit the regional office from inspecting other components or facilities maintained by a provider at the time of the review.

(c) Licensing Determination. A performance-based rating system shall be used to evaluate a provider's compliance with licensing standards. Providers shall attain at least 80 percent compliance overall on each component reviewed. This means that each set of standards within each facility operated by a provider is subject to the 80 percent compliance requirement. If any set of standards within a facility falls below 80 percent compliance, an interim license will be issued for that component. In addition, there may be instances where a component is rated at an 80 percent level of compliance overall but is in substantial noncompliance with standards related to health, safety, and welfare of individuals or staff. This includes significant or chronic violations regarding standards that do not involve direct services to individuals. In such cases, the regional office shall issue an interim license to the provider or take other regulatory action as permitted in Section 397.415, F.S.

(d) Notifying Providers Regarding Disposition on Licensing. In the case of new and renewal applications, the regional office shall give written notice to the applicant as required in Section 120.60(3), F.S., that the regional office has granted or denied its application for a license. In the case of new applicants, this shall occur within the 90-day period following receipt of the completed application. In the case of renewal applicants, this shall occur prior to expiration of the current license.

(e) Reports of Licensing Inspections. The regional offices shall prepare and distribute to providers a report of licensing inspections that shall include:

1. The name and address of the facility;
2. The names and titles of principal provider staff interviewed;

3. An overview of the components and facilities inspected and a brief description of the provider;
4. A summary of findings from each component and facility inspected;
5. A list of noncompliance issues, if any, with rule or statutory references and a request that the provider submit a plan for corrective action, including required completion dates;
6. Recommendations for issuing a probationary, a regular, or an interim license and recommendations regarding other actions permitted under Chapter 397, F.S.; and
7. The name and title of each authorized agent of the Department.

8. If the criteria established for a licensable component are not met, deficiencies must be classified according to the nature and scope of the deficiency and cited as isolated, patterned, or widespread. The type must be identified on the licensing inspection.

(f) Distribution of Licenses and Notices. For new and renewal applications, regional offices shall send providers a written, signed license along with the written notice as described in subparagraph 4 of this section. Additionally, any adverse action by regional offices (e.g., issuance of an interim license, license suspension, denial, revocation, fine or moratorium) shall be accompanied by notice of the right of appeal as required by Chapter 120, F.S.

(g) Content of Licensing Records. The regional offices shall maintain current electronic licensing files on each provider licensed under chapter 397, F.S. The contents of the files shall include those items submitted to the Department, as required in subsections 65D-30.0036(1)-(3), F.A.C., as appropriate, and subparagraph 65D-30.0037(1)(a)5., F.A.C. All documentation and updates will be entered into the Department approved database within 35 business days of changes to the applicant or provider status to ensure contents of licensing records are current.

(h) Listing of Licensed Providers. The regional offices shall maintain a current listing of all licensed providers by components, with license expiration dates as required by Section 397.6774, F.S.

(i) Complaint Log. The regional offices shall electronically document all complaints regarding providers in the data system approved by the Department. Documentation shall include the date the complaint was received, dates review was initiated and completed, and all findings, penalties imposed, fines collected, reports to other licensing or credentialing entities, and other information relevant to the complaint.

(j) Publishing Provider Information. A list of licensed providers shall be published to the Department's website. The list shall include provider name(s), address(es), contact information, number of beds for inpatient services, inspection score, and other information the Department deems useful to the public.

(2) Closing a Licensed Provider. Pursuant to Chapter 120, F.S., providers shall notify the Department in writing at least 30 days prior to ceasing operation. The provider, with the Department's assistance, shall attempt to place all individuals being served in need of care with other providers along with their clinical records and files. The provider shall notify the Department where the clinical records and files of previously discharged individuals are and where they will be stored for the legally required period. A service provider may not engage in patient brokering as established in Section 397.55(2), F.S.

(3) Approval of Overlay Services.

(a) Qualifying as Overlay Services. A provider that is licensed under Chapter 397, F.S., to provide day or night treatment, intensive outpatient treatment, outpatient treatment, aftercare, or intervention is permitted to deliver those component services at locations which are leased or owned by an organization other than the provider, but not by another provider. The aforementioned component services may be delivered under the authority of the provider's current regular license for that component service so that the alternate location will not require a license. To qualify, overlay services shall be provided on a regular or routine basis over time, at an agreed upon location.

(b) Procedure for Approving Overlay Services.

1. The provider shall submit a request to provide overlay services and applicable fee to the Department, including:
 - a. A description of the services to be provided;
 - b. The manner in which services will be provided;
 - c. The number of days each week and the number of hours each day each service will be provided;
 - d. How services will be supervised; and
 - e. The location of the services.
2. The Department shall notify the provider within 30 business days of receipt of the request to provide overlay services of its decision to approve or deny the request and, in the case of denial, reasons for denying the request in accordance with subparagraph 3.

3. The Department shall deny the request to provide overlay services if it determines that the provider did not address the specific items in subparagraph 1., or is currently operating under less than a regular license.

4. In cases where the request to provide overlay services is approved, the Department shall clearly specify the licensed component that will be provided as overlay.

(c) Special Requirements.

1. Services delivered at the alternate site must correspond directly to those permitted under the provider's current license.

2. Information on each individual involved in an overlay service must be maintained in a manner that complies with current licensing requirements.

3. Overlay services are subject to all requirements of the corresponding level of licensure and are subject to inspection by the Department.

4. Overlay services may only be provided at the locations specified by the Department in the approval letter.

(4) Licensing of Department of Juvenile Justice Commitment Programs and Detention Facilities. In instances where substance use services are provided within Juvenile Justice Commitment Programs and detention facilities, such services may be provided in accordance with any one (1) of the four (4) conditions described below:

(a) The services must be provided for the appropriate licensable service component as defined in subsection 65D-30.002(17), F.A.C.;

(b) The services must be provided by employees of a service provider licensed under Chapter 397, F.S.;

(c) The services must be provided by employees of the commitment program or detention facility who are qualified professionals licensed under Chapter 458, 459, 490 or 491, F.S.; or

(d) The services must be provided by an individual who is an independent contractor who is licensed under Chapter 458, 459, 490 or 491, F.S.

(5) Licensing of Department of Corrections Inmate Substance Abuse Programs. Inmate substance abuse services shall be provided within inmate facilities operated by or under contract with the Department of Corrections, or Department of Management Services, as specifically provided for in these rules. The inmate facility is licensed under Chapter 397, F.S., in accordance with the requirements in Rule 65D-30.004, F.A.C., and the appropriate component under Rule 65D-30.007, 65D-30.009, 65D-30.0091, 65D-30.010, 65D-30.011, 65D-30.012 or 65D-30.013, F.A.C.

Rulemaking Authority 397.321(5) FS. Law Implemented 397.321(6), 397.4014, 397.403, 397.407, 397.410 FS. History—New 8-29-19.

65D-30.0038 Violations; Imposition of Administrative Fines; Grounds.

This rule establishes the grounds under which the Department shall issue an administrative fine, as well as the uniform system of procedures to impose disciplinary sanctions.

(1) The Department shall impose an administrative fine for the violation of any provision of rule Chapter 65D-30, F.A.C. or of Chapter 397, F.S., by a licensed service provider, as described in the Substance Use Treatment Facility Licensing Standards Classification of Violations, CF-MH Form 4039, June 2019, which is incorporated by reference. A copy of the Substance Use Treatment Facility Licensing Standards Classification of Violations may be obtained from the Department's website at <http://www.myflfamilies.com/general-information/publications-forms> or from the following links: <http://www.myflfamilies.com/service-programs/substance-abuse/licensure-regulation>, or <http://www.flrules.org/Gateway/reference.asp?No=Ref-10904>. Each standard violation has an assigned classification based on the nature or severity of the violation(s) as identified in CF-MH Form 4039.

(2) The Department shall indicate the classification on the written notice of the violation. The aggregate amount for all fines shall not exceed \$20,000 per inspection.

(3) Definitions.

(a) "Day" means a calendar day in which the program is operating for business.

(b) "Standards" are requirements for the operation of a licensed facility, as provided in statute or in rule.

(c) "Violation" means a finding of noncompliance by the Department of a licensing standard.

(d) Class "I" violations are defined in Section 397.411, F.S., and include all instances where the Department has verified that the licensee is responsible for abuse, neglect, or abandonment of a child or abuse, neglect, or exploitation of a vulnerable adult. "Class I violations" are incidents of noncompliance with a Class I standard as described in CF-MH Form 4039.

(e) Class "II" violations are defined in Section 397.411, F.S. "Class II Violations" are incidents of noncompliance with a Class

II standard as described in CF-MH Form 4039.

(f) Class "III" violations are defined in Section 397.411, F.S. "Class III Violations" are incidents of noncompliance with a Class III standard as described on CF-MH Form 4039.

(g) Class "IV" violations are defined in Section 397.411, F.S. "Class IV Violations" are incidents of noncompliance with a Class IV standard as described on CF-MH Form 4039.

(4) Regardless of the class of violation cited, the Department may impose a sanction on a provider, in addition to the fine, if the operation of any service component or location of the provider has one (1) or more of the violations present as established by Sections 397.415(1)(c) and (d), F.S.

(5) Disciplinary sanctions for licensing violations shall be enforced as follows:

(a) Class I Violations.

1. For the first violation of a Class I standard, the Department shall issue the provider an interim license and impose an administrative fine in an amount not less than \$400 and not exceeding \$500 per day for each violation and may impose other disciplinary sanctions in addition to the fine.

2. For the second and subsequent violation of the same Class I standard, the Department shall suspend, deny, or revoke the license. The Department may also levy a fine not less than \$400 and not exceeding \$500 per day for each violation in addition to any other disciplinary sanction.

(b) Class II Violations.

1. For the first violation of a Class II standard, the Department shall impose a fine not less than \$300 and not exceeding \$400 per day for each violation.

2. For the second violation of the same Class II standard, the Department shall issue the provider an interim license and impose an administrative fine in an amount not less than \$300 and not exceeding \$400 per day for each violation and may impose other disciplinary sanctions in addition to the fine, including suspending, denying, or revoking the license.

3. For the third and subsequent violation of the same Class II standard, the Department shall suspend, deny, or revoke the license. The Department may also levy a fine not less than \$300 and not exceeding \$400 per day for each violation in addition to any other disciplinary sanction.

(c) Class III Violations. When a Class III violation is not corrected within the time specified in the Department's written notice of the violation, the Department shall impose a fine not less than \$200 and not exceeding \$300 per day for each violation.

(d) Class IV Violations. When a Class IV violation is not corrected within the time specified in the Department's written notice of the violation, the Department shall impose a fine not less than \$100 and not exceeding \$200 per day for each violation.

(6) Each day of continuing violation after the date fixed for termination of the violation, as specified by the Department, constitutes an additional, separate, and distinct violation. A grace period is provided, wherein a violation that occurred more than two years prior to a subsequent violation of the same standard will not be counted for purposes of discipline. However, for the purposes of continued licensure, the provider's violation history will be considered.

(7) Any action taken to correct a violation shall be documented in writing by the owner or administrator of the facility and verified through follow-up visits by Department personnel. The Department shall impose a fine and revoke or deny a service provider's license when an administrator fraudulently misrepresents action taken to correct a violation.

(8) The Department shall impose an administrative fine for a violation that is not designated as a Class I, Class II, Class III, or Class IV violation. The amount of the fine shall be \$500 for each violation. Unclassified violations include:

(a) Violating any term or condition of a license;

(b) Violating any provision of applicable rules or authorizing statutes;

(c) Providing services beyond the scope of the license;

(d) Violating a moratorium imposed pursuant to Section 397.415, F.S.;

(e) Failure to submit required incident reports;

(f) Violations that occurred or were identified during the current or preceding licensure year;

(g) Operating a service without a license; and

(h) Failing to inform the Department of a change in ownership within the specified timeframe in accordance with Rule 65D-30.0034, F.A.C.

(9) For purposes of this section, in determining if a penalty is to be imposed for an unclassified violation, the Department shall consider the following factors:

(a) The gravity of the violation, including the probability that death or serious physical or emotional harm to an individual receiving services will result or has resulted, the severity of the action or potential harm, and the extent to which the provisions of the applicable laws or rules were violated;

(b) Actions taken by the owner or administrator to correct violations;

(c) Any previous violations;

(d) The financial benefit to the facility of committing or continuing the violation; and,

(e) The licensed capacity of the facility, if applicable.

(10) Scope of Violations. Each violation of a class standard as described on CF-MH Form 4039 shall be cited as isolated, patterned, or widespread. The scope shall be indicated on the face of the notice of deficiencies in accordance with Section 397.411, F.S. The scope shall determine the fine amount as follows:

(a) For violation(s) cited as isolated, the minimum fine amount for that class standard as allowed under this rule shall be imposed.

(b) For violation(s) cited as patterned, an increase of \$50 from the minimum fine for that class standard amount as allowed under this rule shall be imposed.

(c) For violation(s) cited as widespread, the maximum fine amount for that class standard as allowed under this rule shall be imposed.

(11) Disciplinary sanctions in addition to the fine.

(a) If one or more Class I or Class II licensing violations require the provider to halt service delivery while the violation is remedied, then the license shall be suspended or revoked.

(b) The Department shall consider the factors outlined in Section 397.415(1)(d), F.S. when determining whether a provider's license will be suspended, revoked, or denied renewal.

(c) If as a result of the investigation, the Department makes a decision not to revoke, suspend, or deny further licensure, the Department shall require the provider to prepare a written corrective action plan to correct the deficiencies.

1. The plan shall be in writing and signed by the executive director or designee of the provider;

2. The plan must be approved by the Department before implementation;

3. Failure of the provider to timely comply with the corrective action plan may result in suspension, denial of re-licensure, or revocation of the license.

(d) If as a result of the investigation the Department makes a decision to revoke, suspend, or deny further licensure, notice shall be delivered via personal service or certified mail pursuant to Section 120.60(5), F.S., which shall include the statutory and rule violations that were found, shall advise of the action to be taken, and the right to challenge the action through an administrative proceeding as provided in Chapter 120, F.S.

(12) Documentation Requirements Prior to Administrative Action.

(a) Before making a determination that a license shall be denied, suspended, or revoked, the following shall be documented in the licensing file:

1. All qualifying abuse reports and all reports of licensing violations, and the outcome of any investigations;

2. List of all deficiencies or conditions which compromise the safety or well-being of the individuals in treatment;

3. The length of time and frequency of the noncompliance with the licensing requirements or deficiencies;

4. The date of written notification to the licensee as to the deficiencies and time given to the licensee to correct the deficiencies;

5. The Department's efforts to help the licensee come into compliance; and

6. Barriers, if any, which prohibit the licensee from correcting the deficiencies.

(b) All license revocations and denials shall comply with requirements of Chapter 120, F.S.

(c) All documentation shall be reviewed by the Department's legal counsel prior to administrative action. The notice of revocation or denial shall not be sent to the provider without approval of the Department's legal counsel, except in instances when the Department determines that conditions present a threat to the health, safety, or welfare of an individual in treatment or the public.

Rulemaking Authority 397.321(5), 397.410(2) FS. Law Implemented 397.410, 397.411 FS. History—New 8-29-19.

65D-30.004 Common Licensing Standards.

(1) Operating Procedures. Providers shall demonstrate organizational capability required by paragraph 65D-30.0036(1)(e), F.A.C., through a written, indexed system of policies and procedures that are descriptive of services, and the population served.

Administrative and clinical services must align with current best practices as defined in subsection 65D-30.002(7), F.A.C. All staff shall have a working knowledge of the operating procedures. These operating procedures shall be submitted with new applications and available for review by the Department at any time.

(2) Quality Improvement. Providers shall have a quality improvement program which complies with the requirements established in Section 397.4103, F.S., and which ensures the use of a continuous quality improvement process.

(3) Provider Governance and Management.

(a) Governing Body. Any provider that applies for a license, shall be a legally constituted entity. Providers that are government-based and providers that are for-profit and not-for-profit, as defined in Section 397.311, F.S., shall have a governing body that shall set policy for the provider. The governing body shall maintain a record of all meetings where business is conducted relative to provider operations. These records shall be available for review by the department.

(b) Insurance Coverage. In regard to liability insurance coverage, providers shall assess the potential risks associated with the delivery of services to determine the amount of coverage necessary and shall purchase policies accordingly.

(c) Chief Executive Officer. A chief executive officer shall be appointed. If the entity is operated by a governing board, the governing body shall appoint a chief executive officer. The qualifications and experience required for the position of chief executive officer shall be defined in the provider's operating procedures. Documentation shall be available from the governing body providing evidence that a background screening has been completed in accordance with Chapters 397 and 435, F.S., and there is no evidence of a disqualifying offense. Providers shall notify the regional office in writing within 24 hours when a new chief executive officer is appointed. (Inmate Substance Abuse Programs operated by or under contract with the Department of Corrections, or the Department of Management Services are exempt from the requirements in this paragraph. Juvenile Justice Commitment Programs and detention facilities operated by the Department of Juvenile Justice, are exempt from the requirements of this paragraph.)

(4) Personnel Policies. Personnel policies shall clearly address recruitment and selection of prospective employees, promotion and termination of staff, code of ethical conduct, sexual harassment, confidentiality of individual records, attendance and leave, employee grievance, non-discrimination, abuse reporting procedures, and the orientation of staff to the agency's universal infection control procedures. The code of ethical conduct shall prohibit employees and volunteers from engaging in sexual activity with individuals receiving services for a minimum of two (2) years after the last professional contact with the individual. Providers shall also have a drug-free workplace policy for employees and prospective employees.

(a) Personnel Records. Records on all personnel shall be maintained. Each personnel record shall contain:

1. The individual's current job description with minimum qualifications for the position and documentation that the staff meets the minimum qualifications outlined in the job description;

2. The employment application or resume;

3. The employee's annual performance appraisal;

4. A document signed and dated by the employee indicating that the employee received new staff orientation and understand the personnel policies and the programs operating policies and procedures;

5. A verified or certified copy of degrees, licenses, or certificates of each employee;

6. Documentation of employee screening as required in paragraph (b); and

7. Documentation of required staff training (Inmate Substance Abuse Programs operated by the Department of Corrections are exempt from the provisions of this subparagraph).

(b) Screening of Staff. All owners, chief financial officers, chief executive officers, and clinical supervisors of service providers are subject to level 2 background screening and local background screening as provided under Chapters 435 and 397, F.S. All service provider personnel, and volunteers who have direct contact with children receiving services or with adults with intellectual disabilities receiving services are subject to level 2 background screening as provided under Chapter 435, and Section 397.4073, F.S. In addition, individuals shall be re-screened within five (5) years from the date of their last screening and shall include a local background screening. Re-screening shall include a level 2 screening in accordance with Chapter 435, F.S. Service provider personnel who request an exemption from disqualification must submit the request within 30 days after being notified of the disqualification. If five (5) years or more have elapsed since the most recent disqualifying offense, service provider personnel may work with adults who have substance use disorders under the supervision of a qualified professional until the Department makes a final determination regarding the request for an exemption from disqualification. (Personnel operating directly with local correctional agency or authority, Inmate Substance Abuse Programs operated by or under contract with the Department of Corrections or the Department of Management Services are exempt from the requirements in this paragraph, unless they have direct

contact with unmarried inmates under the age of 18 or with inmates who are intellectually disabled.)

(c) Employment History Checks and Checks of References. The chief executive officer or designee, such as human resources staff, shall assess employment history checks and checks of references for each employee who has direct contact with children receiving services or adults who are intellectually disabled receiving services.

(5) Standards of Conduct. Providers shall establish written rules of conduct for individuals. Each individual receiving services shall be given rules of conduct during orientation to be reviewed, signed and dated.

(6) Medical Director. This requirement applies to addictions receiving facilities, detoxification, intensive inpatient treatment, residential treatment, and methadone and medication-assisted treatment for opioid addiction. Providers shall designate a medical director who shall oversee all medical services. The medical director’s responsibilities shall be clearly described.

(a) The Medical Director shall have overall responsibility for the following:

1. Medical services provided by the program;
2. Oversight of the development and revision of medical policies, including:
 - a. The means for the detection and referral of health problems through medical surveillance and regular examination;
 - b. Implementation of medical orders regarding treatment of medical conditions;
 - c. Reporting of communicable diseases and infections in accordance with federal and state laws;
 - d. Procedures and ongoing training for routine medical care, specialized services, specialized medications, and medical and psychiatric emergency care;
3. Collaborative supervision with the clinical supervisor of non-medical staff in the provision of substance use disorder services; and
4. Supervision of medical staff in the performance of medical services.

(b) The Medical Director must meet at least twice a year with the risk management and quality assurance program of the facility to review incident reports, grievances, and complaints to identify and implement processes to reduce clinical risks and safety hazards. This process shall be documented in the risk management and quality assurance committee meeting minutes. When the Medical Director is the attending physician of an individual receiving services, they shall participate in the development of the treatment plan.

(c) The Department shall utilize the following methodology for determining the maximum number of individuals a medical director may serve pursuant to Section 397.410(1)(c)5., F.S.:

Component	Average Length of Stay (LOS) in Days	Total Service Time over LOS	Work Days	Work Days per LOS	Hours worked per LOS (Work Days x Work Days per LOS)	Calculation (Time in LOS/Total Service Time)	Total Case Load
Inpatient Detoxification	4 days	1.0 hour*	8 hours	4 days	32 hours	32 /1 hour	32 individuals
Outpatient Detoxification	5 days	1.2 hours*	8 hours	5 days	40 hours	40/1.2 hours	33 individuals
Residential Level I	19 days	1 hour**	8 hours	15 days	120 hours	120/1 hour	120 individuals
Residential Level II	41 days	1.75 hours**	8 hours	30 days	240 hours	240/1.75	137 individuals
Residential Level III	54 days	2.25 hours**	8 hours	40 days	320 hours	320/2.25	142 individuals
Residential Level IV	42 days	1.75 hours**	8 hours	30 days	240 hours	240/1.75	137 individuals
Medication and Methadone Maintenance	1,030 days	3.25 hours***	8 hours	709 days	5,672 hours	5,672/3.25	1,745 individuals

*Service Times: New Patient Visit (30 minutes), Daily Follow-up (10 minutes)

**Service Times: New Patient Visit (30 minutes), Weekly Follow-up (15 minutes)

***Service Times: New Patient Visit (30 minutes), Quarterly Follow-up (15 minutes)

(d) A medical director may not serve in that capacity for more than a maximum of the indicated number of individuals for the treatment types listed below:

1. Addiction receiving facilities, inpatient detoxification, and intensive inpatient providers – a cumulative total of 32 individuals at any given time.

2. Outpatient detoxification – a cumulative total of 33 individuals at any given time.

3. Residential treatment (level 1) – a cumulative total of 120 individuals at any given time.

4. Residential treatment (level 2) – a cumulative total of 137 individuals at any given time.

5. Residential treatment (level 3) – a cumulative total of 142 individuals at any given time.

6. Residential treatment (level 4) – a cumulative total of 137 individuals at any given time.

7. Medication and methadone maintenance treatment – a cumulative total of 1,745 individuals at any given time.

(e) Providers licensed for multiple service components shall ensure compliance with this medical director standard by applying the percentage of time dedicated to each service component to the Department's methodology for maximum individuals served. This information shall be submitted with the application for licensure and updated at the time of any licensure renewal. The provider shall be responsible for providing documentation to support the case load maximum upon request.

(f) A provider may not operate without a medical director on staff at any time. When a medical director is not available, the medical director shall ensure that a qualified physician who is available is designated. Upon the departure of a medical director, an interim medical director shall be appointed. The provider shall notify the regional office in writing within 24 hours when there is a change in the medical director, provide proof that the new or interim medical director holds a current license in the state of Florida, and is free of administrative action(s) against their license.

(g) In cases where a provider operates treatment components that are not identified in this subsection, the provider shall have access to a physician through a written agreement who will be available to consult on any medical services required by individuals involved in those components. Physicians serving as a medical consultant shall adhere to all requirements and restrictions as described for medical directors in this chapter.

(h) A medical director or medical consultant in violation of any of the requirements set forth in Chapter 65D-30, F.A.C., or Chapter 397, F.S., is permanently barred from being employed by or contracting with a service provider.

(7) Medical Services.

(a) Written Medical Provisions. For components identified in subsection 65D-30.004(6), F.A.C., each physician working with a provider shall establish written protocols for the provision of medical services pursuant to Chapters 458 and 459, F.S., and for managing medication according to medical and pharmacy standards, pursuant to Chapter 465, F.S. Such protocols will be implemented only after written approval by the chief executive officer and medical director.

(b) The medical protocols shall also include:

1. The manner in which certain medical functions may be delegated to Advanced Registered Nurse Practitioners and Physician's Assistants in those instances where these practitioners are utilized as part of the clinical staff;

2. Issuing orders; and

3. Signing and countersigning results of physical health assessments;

4. Procedures shall be documented for the administration of medication by a qualified medical professional as authorized by their scope of practice.

(c) Supervision of self-administration of medication may be provided, including at the community housing location, under the following conditions:

1. A secure, locked storage for medications must be maintained;

2. Individuals must receive prescription medication in accordance to the prescriptions of qualified physicians, as required by law;

3. Supervision of self-administration of medication must be provided by trained personnel in accordance with paragraph 65D-30.0046(1)(f), F.A.C. of this chapter.

4. A record of all instances of supervision of self-administration of medication shall be maintained in a medication observation record, to include the date, time, and dosage in accordance to the prescription. The personnel who witnessed the self-administration of the medication shall sign and date the medication observation record.

(d) All medical protocols shall be reviewed and approved by the medical director and chief executive officer on an annual basis and shall be available for review by the Department.

(e) Emergency Medical Services. All licensed providers shall describe the manner in which medical emergencies shall be addressed. (Inmate Substance Abuse Programs operated by or under contract with the Department of Corrections or the Department of Management Services are exempt from the requirements of subsection 65D-30.004(7), F.A.C. Juvenile Justice Commitment Programs and detention facilities operated by or under contract with the Department of Juvenile Justice are exempt from the requirements of this subsection.)

(8) State Approval Regarding Prescription Medication. In instances where the provider utilizes prescription medication, medications shall be purchased, handled, dispensed, administered, and stored in compliance with the State of Florida Board of Pharmacy requirements for facilities which hold Modified Class II Institutional Permits and in accordance with Chapter 465, F.S. This shall be implemented in consultation with a state-licensed consultant pharmacist and approved by the medical director. The provider shall ensure that policies implementing this subsection are reviewed and signed and dated annually by a state-licensed consultant pharmacist. (Inmate Substance Abuse Programs operated by or under contract with the Department of Corrections, the Department of Juvenile Justice, or the Department of Management Services are exempt from the requirements of this subsection.) All providers purchasing, dispensing, handling, administering, storing, or observing self-administration of medications shall adhere to best practices, state and federal regulations.

(9) Universal Infection Control. This requirement applies to addictions receiving facilities, detoxification, intensive inpatient treatment, residential treatment, day or night treatment with community housing, day or night treatment, intensive outpatient treatment, outpatient treatment, and medication-assisted treatment for opioid addiction.

(a) Plan for Exposure Control.

1. A written plan for exposure control regarding infectious diseases shall be developed and shall apply to all staff, volunteers, and individuals receiving services. The plan shall be initially approved and reviewed annually by the medical director or consulting physician. The plan shall be in compliance with Chapters 381 and 384, F.S., and in accordance with the Department of Health's requirements as stated in Chapters 64D-2 and 64D-3, F.A.C. The plan shall be signed and dated by the medical director or consulting physician as required by this paragraph.

2. The plan shall be consistent with the protocols and facility standards published in the Federal Centers for Disease Control and Prevention Guidelines and Recommendations for Infectious Diseases.

(b) Required Services. The following Universal Infection Control Services shall be provided:

1. Risk assessment and screening individuals for both high-risk behavior and symptoms of communicable disease as well as actions to be taken on behalf of individuals identified as high-risk and individuals known to have an infectious disease;

2. HIV and TB testing and HIV pre-test and post-test counseling to high-risk individuals, provided directly or through referral to other healthcare providers which can offer the services; and

3. Reporting of communicable diseases to the Department of Health in accordance with Sections 381.0031 and 384.25, F.S. (Inmate Substance Abuse Programs operated by or under contract with the Department of Corrections or Department of Management Services are exempt from the requirements of this subsection but shall provide such services as required by Chapter 945, F.S., titled Department of Corrections. Juvenile Justice Commitment Programs and detention facilities operated by or under contract with the Department of Juvenile Justice are exempt from the requirements of this subsection but shall provide such services as required in the policies, standards, and contractual conditions established by the Department of Juvenile Justice.)

(10) Universal Infection Control Education Requirements for Employees and Individuals. Providers shall meet the educational requirements for HIV and AIDS pursuant to Section 381.0035, F.S., and all infection prevention and control educational activities shall be documented. (Inmate Substance Abuse Programs operated by or under contract with the Department of Corrections, the Department of Juvenile Justice, or the Department of Management Services are exempt from the requirements of this subsection but shall provide such services as required in the policies, standards, and contractual conditions established by the Department of Juvenile Justice.)

(11) Meals. At least three (3) meals per calendar day shall be provided to individuals in addictions receiving facilities, inpatient detoxification, intensive inpatient treatment, and residential treatment. In addition, at least one (1) snack shall be provided each day. For day or night treatment with community housing and day or night treatment, the provider shall make arrangements to serve a meal to individuals involved in services a minimum of five (5) hours at any one time. Individuals with special dietary needs shall be reasonably accommodated. Under no circumstances may food be withheld for disciplinary reasons. The provider shall document and

ensure that nutrition and dietary plans are reviewed and approved by a dietitian/nutritionist licensed under Section 468.509, F.S., at least annually. (Inmate Substance Abuse Programs operated by or under contract with the Department of Corrections, the Department of Juvenile Justice, or the Department of Management Services are exempt from the requirements of this subsection but shall provide such services as required in the policies, standards, and contractual conditions established by the respective department.)

(12) Verbal De-escalation. This applies to all components with the exception of universal direct and indirect prevention services. Providers shall have written policies and procedures of the specific verbal de-escalation technique(s) to be used. Direct care staff shall be trained in verbal de-escalation techniques as required in paragraph 65D-30.0046(1)(b), F.A.C. The provider shall provide proof to the Department that affected staff have completed training in those techniques.

(13) Compulsory School Attendance for Minors. Providers which admit juveniles between the ages of 6 and 16 shall comply with Chapter 232, F.S., entitled Compulsory School Attendance; Child Welfare.

(14) Data. Providers shall report data to the department pursuant to Section 397.321(3)(c), F.S.

(15) Special In-Residence Requirements. Service providers housing individuals for treatment shall only furnish beds to individuals admitted for substance use treatment for the specific level of care for which the individuals meet criteria. Providers that house males and females together within the same facility shall provide separate sleeping arrangements for these individuals and must have at least one staff member present at all times. Providers which serve adults in the same facility as persons under 18 years of age shall ensure individual safety with one-on-one supervision, separate bedrooms, and programming according to age. Providers, aside from Juvenile Justice Commitment Programs and detention facilities operated by or under contract with the Department of Juvenile Justice, shall not collocate children or adolescents with adults. Admitted seventeen-year-olds who turn 18 while completing treatment shall be allowed to stay only if it is clinically indicated, there is one-on-one supervision, and they have separate bedrooms.

(16) Reporting of Abuse, Neglect, and Deaths. Providers shall adhere to the statutory requirements for reporting abuse, neglect, and deaths of children under Chapter 39, F.S., and of adults under Sections 415.1034 and 397.501(7)(c), F.S.

(17) Critical Incident Reporting Pursuant to Section 397.4103(2)(f), F.S.

(a) Every provider shall develop policies and procedures for submitting critical incidents into the Department's statewide designated electronic system specific to critical incident reporting.

(b) Every provider shall report the following critical incidents within 24 hours of the incident occurring.

1. Adult Death. An individual 18 years old or older whose life terminates:

a. While receiving services; or

b. When it is known that an adult died within thirty (30) days of discharge from a program.

c. The final classification of an adult's death is determined by the medical examiner. In the interim, the manner of death shall be reported as one of the following:

(I) Accident. A death due to the unintended actions of one's self or another.

(II) Homicide. A death due to the deliberate actions of another.

(III) Natural Expected. A death that occurs, because of, or from complications of, a diagnosed illness for which the prognosis is terminal.

(IV) Natural Unexpected. A sudden death that was not anticipated and is attributed to an underlying disease either known or unknown prior to the death.

(V) Suicide. The intentional and voluntary taking of one's own life.

(VI) Undetermined. The manner of death has not yet been determined.

(VII) Unknown. The manner of death was not identified or made known.

2. Adolescent Arrest. The arrest of an adolescent.

3. Adolescent Death. An individual who is less than 18 years of age whose life terminates:

a. While receiving services; or

b. When it is known that an adolescent died within 30 days of discharge from a program;

c. The final classification of an adolescent's death is determined by the medical examiner. In the interim, the manner of death will be reported as one of the following:

(I) Accident. A death due to the unintended actions of one's self or another.

(II) Homicide. A death due to the deliberate actions of another.

(III) Natural Expected. A death that occurs, because of, or from complications of, a diagnosed illness for which the prognosis is

terminal.

(IV) Natural Unexpected. A sudden death that was not anticipated and is attributed to an underlying disease either known or unknown prior to the death.

(V) Suicide. The intentional and voluntary taking of one's own life.

(VI) Undetermined. The manner of death has not yet been determined.

(VII) Unknown. The manner of death was not identified or made known.

4. Adolescent-on-Adolescent Sexual Abuse. Any sexual behavior between adolescents less than 18 years of age which occurs without consent, without equality, or because of coercion.

5. Elopement. An unauthorized absence of any individual.

6. Employee Arrest. The arrest of an employee for a civil or criminal offense.

7. Employee Misconduct. Work-related conduct or activity of an employee that results in potential liability for the Department; death or harm to an individual receiving services; abuse, neglect or exploitation of a vulnerable adult; or which results in a violation of statute, rule, regulation, or policy. This includes falsification of records; failure to report suspected abuse, neglect, or abandonment of a child; contract mismanagement; or improper commitment or expenditure of state funds.

8. Missing Adolescent. When the whereabouts of an adolescent in the custody of the Department are unknown and attempts to locate the adolescent have been unsuccessful.

9. Security Incident – Unintentional. An unintentional action or event that results in compromised data confidentiality, a danger to the physical safety of personnel, property, or technology resources; misuse of state property or technology resources; or, denial of use of property or technology resources. This excludes instances of compromised information of individuals in treatment.

10. Sexual Abuse/Sexual Battery. Any unsolicited or non-consensual sexual activity by one individual receiving services to another individual receiving services; or, sexual activity by a service provider employee or other person to an individual receiving services, or an individual receiving services to an employee regardless of the consent of the individual receiving services. This may include sexual battery, as defined in Chapter 794, F.S.

11. Significant Injury to Individuals in Treatment. Any severe bodily trauma received by an individual in a program that requires immediate medical or surgical evaluation or treatment in a hospital emergency department to address and prevent permanent damage or loss of life.

12. Significant Injury to Staff. Any serious bodily trauma received by a staff member as result of a work-related activity that requires immediate medical or surgical evaluation or treatment in a hospital emergency department to prevent permanent damage or loss of life.

13. Suicide Attempt. A potentially lethal act which reflects an attempt by an individual to cause his or her own death as determined by a licensed mental health professional or other licensed healthcare professional.

14. Other. Any major event not previously identified as a reportable critical incident but has, or is likely to have, a significant impact on individuals receiving services, on the Department, such as:

a. Human acts that jeopardize the health, safety, or welfare of individuals receiving services, such as kidnapping, riot, or hostage situation;

b. Bomb or biological/chemical threat of harm to personnel or property involving an explosive device or biological/chemical agent received in person, by telephone, in writing, via mail, electronically, or otherwise;

c. Theft, vandalism, damage, fire, sabotage, or destruction of state or private property of significant value or importance;

d. Death of an employee or visitor while on the grounds of the facility;

e. Significant injury of a visitor while on the grounds of the facility that requires immediate medical or surgical evaluation or treatment in a hospital emergency department to prevent permanent damage or loss of life; or

f. Events regarding individuals receiving services or providers that have led to or may lead to media reports.

(18) Confidentiality. Providers shall comply with Title 42, Code of Federal Regulations, Part 2, titled "Confidentiality of Alcohol and Drug Abuse Patient Records," and with Sections 397.501(7) and 397.752, F.S., regarding confidential individual information.

(19) Certified Recovery Residence Referrals. Providers shall comply with the statutory requirements established in Section 397.4873, F.S., regarding referrals to and admissions from certified recovery residences. All providers shall maintain an active referral log of each individual referred to a recovery residence. The log shall include the individual's name being referred or accepted, name and address of the certified recovery residence, signature of the employee making the referral, and date of the

referral. The log shall be made available for review by the Department. (Service Providers under contract with the Managing Entities are exempt from this requirement.)

(20) Telehealth Services.

Prior to initiating services utilizing telehealth, providers shall submit detailed procedures outlining which services they intend to provide as described in paragraph 65D-30.003(1)(l), F.A.C. Providers delivering any services by telehealth are responsible for the quality of the equipment and technology employed and are responsible for its safe use. Providers utilizing telehealth equipment and technology must be able meet or exceed the prevailing standard of care. Service providers must meet the following additional requirements:

(a) Must be capable of two (2)-way, real-time electronic communication, and the security of the technology must be in accordance with applicable federal confidentiality regulations 45 CFR §164.312;

(b) The interactive telecommunication equipment must include audio and high-resolution video equipment which allows the staff providing the service to clearly understand and view the individual receiving services;

(c) Clinical screenings, assessments, medication management, and counseling are the only services allowable through telehealth; and

(d) Telehealth services must be provided within the state of Florida except for those licensed for outpatient, intervention, and prevention.

(21) Group Counseling. The maximum number of individuals allowed in a group session is 15.

(22) Overdose Prevention.

(a) All providers must develop overdose prevention plans. All staff must have a working knowledge of the overdose prevention plan. Overdose prevention plans shall include:

1. Education about the risks of overdose, including having a lower tolerance for opioids if the individual is participating in an abstinence-based treatment program or is being discharged from a medication-assisted treatment program.

2. Information about Naloxone, the medication that reverses opioid overdose, including how to use Naloxone and where and how to access it.

(b) Providers who maintain an emergency overdose prevention kit must develop and implement a plan to train staff in the prescribed use and the availability of the kit for use during all program hours of operation.

(c) Overdose prevention information, as described in subparagraphs (22)(a)1. and 2. of this rule, must be shared with individuals upon admission.

(d) Providers must offer overdose prevention information, as described in subparagraphs (22)(a)1. and 2. of this rule, to individuals placed on a waitlist to receive treatment services.

Rulemaking Authority 397.321(5) FS. Law Implemented 397.321, 397.4014, 397.4073, 397.4075, 397.410, 397.4103, 397.411 FS. History—New 5-25-00, Amended 4-3-03, 12-12-05, 8-29-19.

65D-30.0041 Clinical Records.

(1) Record Management System. Clinical records shall be kept secure from unauthorized access and maintained in accordance with 42 Code of Federal Regulations, Part 2 and Section 397.501(7), F.S. Providers shall have record management procedures regarding content, organization, access, and use of records.

The record management system shall meet the following additional requirements:

(a) Original clinical records shall be signed in ink and by hand or electronically;

(b) Record entries shall be legible;

(c) In instances where records are maintained electronically, a staff identifier code will be accepted in lieu of a signature;

(d) Documentation within records shall not be deleted; and

(e) Amendments or marked-through changes shall be initialed and dated by the individual making such changes.

(2) Record Retention and Disposition. In the case of individual clinical records, records shall be retained for a minimum of seven (7) years. The disposition of clinical records shall be carried out in accordance with Title 42, Code of Federal Regulations, Part 2, and Section 397.501(7), F.S. If any litigation claim, negotiation, audit, or other action involving the records has been started before the expiration of the seven-year period, the records shall be retained until completion of the action and resolution of all issues which arise from such actions. (Juvenile Justice commitment programs and detention facilities operated by or under contract with the Department of Juvenile Justice, Inmate Substance Abuse Programs operated by or under contract with the Department of

Corrections or the Department of Management Services are exempt from these requirements.) found in the Children and Families Operating Procedures (CFOP) 15-4, Records Management, and Children and Families Pamphlet (CFP) 15-7, Records Retention Schedule. Juvenile Justice Commitment Programs and detention facilities operated by or under contract with the Department of Juvenile Justice are exempt from the requirements found in the Children and Family Services Operating Procedures (CFOP) 15-4, Records Management, and the Children and Families Pamphlet (CFP) 15-7, Records Retention Schedule.)

(3) Information Required in Clinical Records.

(a) The following applies to addictions receiving facilities, detoxification, intensive inpatient treatment, residential treatment, day or night treatment with community housing, day or night treatment, intensive outpatient treatment, outpatient treatment, and methadone medication-assisted treatment for opioid addiction. Information shall include:

1. Name and address of the individual receiving services and referral source;
2. Screening information;
3. Voluntary informed consent for treatment or an order to treatment for involuntary admissions and for criminal and juvenile justice referrals;
4. Informed consent for a drug screen, when conducted;
5. Informed consent for release of information;
6. Documentation of individual orientation;
7. Physical health assessment, when conducted;
8. Psychosocial assessment, except for detoxification;
9. Diagnostic services, when provided;
10. Individual placement information, including the signature of the person who recommended placement at the level of care;
11. Abbreviated treatment plan, for addictions receiving facilities and detoxification;
12. Initial treatment plans, where indicated, and treatment plans and subsequent reviews, except for addictions receiving facilities and detoxification;
13. Progress notes;
14. Record of ancillary services, when provided;
15. Record of medical prescriptions and medication, when provided;
16. Reports to the criminal and juvenile justice systems, when provided;
17. Copies of service-related correspondence generated or received by the provider, when available;
18. Transfer summary, if transferred; and
19. A discharge summary.

In the case of clinical records developed and maintained by the Department of Corrections or the Department of Management Services on inmates participating in inmate substance abuse programs, or Juvenile Justice Commitment Programs and detention facilities operated by or under contract with the Department of Juvenile Justice, such records shall not be made part of information required in subparagraph (1)(c) above.

(b) Records regarding substance use treatment shall be made available to authorized agents of the Department only on a need-to-know basis.

(c) The following applies to aftercare. Information shall include:

1. A description of the individual's treatment episode;
2. Informed consent for services;
3. Informed consent for drug screen, when conducted;
4. Informed consent for release of information;
5. Aftercare plan;
6. Documentation assessing progress;
7. Record of ancillary services, when provided;
8. A record of medical prescriptions and medication, when provided;
9. Reports to the criminal and juvenile justice systems, when provided;
10. Copies of service-related correspondence generated or received by the provider;
11. Transfer summary, if transferred; and
12. A discharge summary.

(d) The following applies to intervention. Information shall include:

1. Name and address of individual and referral source;
2. Screening information;
3. Informed consent for services;
4. Informed consent for a drug screen, when conducted;
5. Informed consent for release of information;
6. Individual placement information, with the exception of case management;
7. Intervention plan, when required;
8. Summary notes;
9. Record of ancillary services, when provided;
10. Reports to the criminal and juvenile justice systems, when provided;
11. Copies of service-related correspondence generated or received by the provider;
12. A transfer summary, if transferred; and
13. A discharge summary.

(e) The following applies to indicated prevention. Information shall include:

1. Identified risk and protective factors for the target population;
2. Record of activities including description, date, duration, purpose, and location of service delivery;
3. Tracking of individual attendance;
4. Individual demographic identifying information;
5. Informed consent for services;
6. Prevention plan;
7. Summary notes;
8. Informed consent for release of information;
9. Completion of services summary of individual involvement and follow-up information; and
10. Transfer summary, if referred to another placement.

Rulemaking Authority 397.321(5) FS. Law Implemented 397.321(3)(c), 397.4014, 397.410, 397.4103 FS. History--New 8-29-19.

65D-30.0042 Clinical and Medical Guidelines.

(1) Screening. This requirement applies to addictions receiving facilities, detoxification, intensive inpatient treatment, residential treatment, day or night treatment with community housing, day or night treatment, intensive outpatient treatment, outpatient treatment, medication-assisted treatment for opioid addiction, and intervention. If the screening is not completed by a qualified professional, then it shall be countersigned and dated by a qualified professional.

(a) Determination of Need and Eligibility for Placement. The condition and needs of the individual shall dictate the urgency and timing of screening; screening is not required if an assessment is completed at time of admission. All individuals presenting for services, voluntarily or involuntarily, shall be evaluated to determine service needs and eligibility for placement or other disposition. The person conducting the screening shall document the rationale for any action taken and the validated tool used for service determination.

(b) Consent for Drug Screen. If required by the circumstances pertaining to the individual's need for screening, or dictated by the standards for a specific component, individuals shall give informed consent for a drug screen.

(c) Consent for Release of Information. Consent for the release of information shall include information required in 42 Code of Federal Regulations, Part 2, and may be signed by the individual only if the form is complete.

(d) Consent for Services. A consent for services form shall be signed by the individual prior to or upon placement, with the exception of involuntary placements.

(2) Assessment. This requirement applies to addictions receiving facilities, detoxification, intensive inpatient treatment, residential treatment, day or night treatment with community housing, day or night treatment, intensive outpatient treatment, outpatient treatment, and methadone medication-assisted treatment for opioid addiction. Individuals shall undergo an assessment of the nature and severity of their substance use disorder. The assessment shall include a physical health assessment and a psychosocial assessment.

(a) Physical Health Assessment. (Inmate Substance Abuse Programs operated by or under contract with the Department of

Corrections or Department of Management Services are exempt from the requirements of this paragraph. Juvenile Justice Commitment Programs and detention facilities operated by or under contract with the Department of Juvenile Justice are exempt from the requirements of this subsection.)

1. Nursing Physical Screen. An in-person nursing physical screen shall be completed on each person considered for placement in addictions receiving facilities, detoxification, or intensive inpatient treatment. The screen shall be completed by a L.P.N., R.N., A.P.R.N., or physician's assistant, or physician. When completed by a L.P.N., it shall be countersigned by a R.N., A.P.R.N. physician's assistant, or physician. The results of the screen shall be documented by the physician, nurse, or physician's assistant providing the service and signed and dated by that person. If the nursing physical screen is completed in lieu of a medical history, further action shall be in accordance with the medical protocol established under subsection 65D-30.004(7), F.A.C.

2. Medical History. A medical history shall be completed on each individual.

a. For intensive inpatient treatment, the history shall be completed within one (1) calendar day of placement. In cases where an individual is placed directly into intensive inpatient treatment from detoxification or residential treatment, the medical history completed on the individual while in detoxification or residential treatment may be accepted.

b. For residential treatment and methadone medication-assisted treatment for opioid addiction, the history shall be completed within 30 calendar days prior to placement, or within one (1) calendar day of placement.

c. For day or night treatment with community housing, day or night treatment, intensive outpatient treatment, and outpatient treatment, a medical history shall be completed within 30 calendar days prior to or upon placement.

For the components identified in sub-subparagraphs 2.a. and 2.b., the medical history shall be completed by the physician, or in accordance with the medical protocol established in subsection 65D-30.004(7), F.A.C. Further, the history shall be reviewed, signed and dated by the physician in accordance with the medical protocol established in subsection 65D-30.004(7), F.A.C. For the components identified in sub-subparagraph 2.c., the medical history shall be completed by the individual or the individual's legal guardian. For all components, the medical history shall be maintained in the clinical record and updated annually if an individual remains in treatment for more than one (1) year.

3. Physical Examination. A physical examination shall be completed on each individual in the level of service indicated below.

a. For addictions receiving facilities and detoxification, the physical examination shall be completed within seven (7) calendar days prior to placement or two (2) calendar days after placement.

b. For intensive inpatient treatment, the physical examination shall be completed within seven (7) calendar days prior to placement or within one (1) calendar day of placement. In cases where an individual is placed directly into intensive inpatient treatment from detoxification or residential treatment, the physical examination completed on the individual while in detoxification or residential treatment may be accepted.

c. For residential treatment, the physical examination shall be completed within 30 calendar days prior to placement or three (3) calendar days after placement. In cases where an individual is placed directly into residential treatment from detoxification or intensive inpatient treatment, the physical examination completed on the individual while in detoxification or intensive inpatient treatment may be accepted.

d. For methadone medication-assisted treatment for opioid addiction, the physical examination shall be completed prior to administration of the initial dose of methadone. In emergency situations the initial dose may be administered prior to the examination. Within five calendar days of the initial dose, the physician shall document in the clinical record the circumstances that prompted the emergency administration of methadone and sign and date these entries.

For components identified in sub-subparagraphs 3.a.-d., the physical examination shall be completed by the physician, or in accordance with the medical protocol established in subsection 65D-30.004(7), F.A.C. Further, the examination shall be reviewed, signed and dated by the physician in accordance with the medical protocol established in subsection 65D-30.004(7), F.A.C. In cases where an individual is placed directly into residential treatment from detoxification or intensive inpatient treatment, the physical examination completed on the individual while in detoxification or intensive inpatient treatment may be accepted.

4. Laboratory Tests. Individuals shall provide a sample for testing blood and urine, including a drug screen.

a. For addictions receiving facilities, inpatient detoxification, intensive inpatient treatment, and residential treatment, all laboratory tests will be performed in accordance with the medical protocol established in subsection 65D-30.004(7), F.A.C. Further, the results of the laboratory tests shall be reviewed, signed and dated during the assessment process and in accordance with the medical protocol established in subsection 65D-30.004(7), F.A.C.

b. For medication-assisted treatment for opioid addiction, blood and urine samples shall be taken within seven (7) calendar days

prior to placement or two (2) calendar days after placement. A drug screen shall be conducted at the time of placement. If there are delays in the procedure, such as problems in obtaining a blood sample, this shall be documented by a licensed nurse in the individual record. The initial dose of medication may be given before the laboratory test results are reviewed by the physician. The results of the laboratory test shall be reviewed, signed and dated by the physician, or in accordance with the medical protocol established in subsection 65D-30.004(7), F.A.C.

5. Pregnancy Test. This requirement applies to addictions receiving facilities, detoxification, intensive inpatient treatment, residential treatment, and methadone medication-assisted treatment for opioid addiction. Female individuals shall be evaluated by a physician, or in accordance with the medical protocol established in subsection 65D-30.004(7), F.A.C., to determine the necessity of a pregnancy test. In cases where it is determined necessary, individuals shall be provided testing services directly or be referred within 24 hours following placement.

6. Tests for Sexually Transmitted Diseases and Tuberculosis. A screening for sexually transmitted diseases, HIV, hepatitis, and tuberculosis shall be conducted. For a screening result indicating the individual is at-risk for any of these conditions, the provider shall conduct testing or make testing available through appropriate referral, in instances where a provider cannot or does not provide the testing. The individual may refuse the screening or the testing, and the provider shall document the refusal. Department of Health testing requirements can be found in Rule 64D-2.004 and Chapter 64D-3, F.A.C.

a. For intensive inpatient treatment, and residential treatment, tests will be conducted within the time frame specified for the physical examination. The results of both tests shall be reviewed and signed and dated by the physician, or in accordance with the medical protocol established in subsection 65D-30.004(7), F.A.C., and filed in the individual's clinical record.

b. For methadone medication-assisted treatment for opioid addiction, the tests will be conducted at the time samples are taken for other laboratory tests. Positive results shall be reviewed and signed and dated by a physician, or in accordance with the medical protocol established in subsection 65D-30.004(7), F.A.C.

7. Special Medical Problems. Particular attention shall be given to individuals with special medical problems or needs. This includes referral for medical services. A record of all such referrals shall be maintained in the individual record.

8. Additional Requirements for Intensive Inpatient Treatment, and Residential Treatment. If an individual is readmitted within 90 calendar days of discharge to the same provider, a physical examination shall be conducted as prescribed by the physician. If an individual is readmitted to the same provider after 90 calendar days of the discharge date, the individual shall receive a complete physical examination.

9. Additional Requirements for Methadone Medication-Assisted Treatment for Opioid Addiction.

a. The individual's current addiction and history of addiction shall be recorded in the individual record by the physician, or in accordance with the medical protocol established in subsection 65D-30.004(7), F.A.C. In any case, the record of the individual's current substance use and history of substance use shall be reviewed, signed and dated by the physician, or in accordance with the medical protocol established in subsection 65D-30.004(7), F.A.C.

b. A physical examination shall be conducted on individuals who are placed directly into treatment from another provider unless a copy of the examination accompanies the individual and the examination was completed within the year prior to placement. In instances where a copy of the examination is not provided because of circumstances beyond the control of the referral source, the physician shall conduct a physical examination within five calendar days of placement.

(b) Psychosocial Assessment.

1. Information Required. The psychosocial assessment shall include the individual's history as determined through an assessment of the following items:

- a. Emotional or mental health;
- b. Level of substance use impairment;
- c. Family history, including substance use by other family members;
- d. The individual's substance use history, including age of onset, choice of drugs, patterns of use, consequences of use, and types and duration of, and responses to, prior treatment episodes;
- e. Educational level, vocational status, employment history, and financial status;
- f. Social history and functioning, including support network, family and peer relationships, and current living conditions;
- g. Past or current sexual, psychological, or physical abuse or trauma;
- h. Individual's involvement in leisure and recreational activities;
- i. Cultural influences;

j. Spiritual or values orientation;

k. Legal history and status;

l. Individual's perception of strengths and abilities related to the potential for recovery; and

m. A clinical summary, including an analysis and interpretation of the results of the psychosocial assessment.

n. Documentation of determination of placement utilizing a validated tool used for service determination.

o. Documentation of appropriateness of level of care countersigned by the qualified professional or clinical supervisor.

2. Requirements for Components. Any psychosocial assessment that is completed within 30 calendar days prior to placement in any component identified in sub-subparagraphs a.-f. below may be accepted by the provider placing the individual. Otherwise, the psychosocial assessment shall be completed according to the following schedule:

a. For addictions receiving facilities, the psychosocial assessment shall be completed within three (3) calendar days of placement, unless clinically contraindicated;

b. For intensive inpatient treatment, the psychosocial assessment shall be completed within three (3) calendar days of placement;

c. For residential treatment level 1, the psychosocial assessment shall be completed within five (5) calendar days of placement;

d. For residential treatment levels 2, 3, 4, day or night treatment with community housing, and day or night treatment, the psychosocial assessment shall be completed within 10 calendar days of placement;

e. For intensive outpatient treatment and outpatient treatment, the psychosocial assessment shall be completed within 30 calendar days of placement; and

f. For methadone medication-assisted treatment for opioid addiction, the psychosocial assessment shall be completed within 15 calendar days of placement.

3. Psychosocial Assessment Sign-off Requirements. The psychosocial assessment shall be completed by clinical staff and signed and dated. If the psychosocial assessment was not completed initially by a qualified professional, the psychosocial assessment shall be reviewed, countersigned, and dated by a qualified professional within 10 calendar days of completion. (Inmate Substance Abuse Programs operated by or under contract with the Department of Corrections or the Department of Management Services shall conduct the review and sign-off within 30 calendar days.)

4. Psychosocial Assessment Readmission Requirements. In instances where an individual is readmitted to the same provider for services within 180 calendar days of discharge, a psychosocial assessment update shall be conducted, if clinically indicated. Information to be included in the update shall be determined by the qualified professional. A new assessment shall be completed on individuals who are readmitted for services more than 180 calendar days after discharge. In addition, the psychosocial assessment shall be updated annually for individuals who are in continuous treatment for longer than one (1) year.

5. Assessment Requirements Regarding Individuals Who Are Referred or Transferred.

a. A new psychosocial assessment does not have to be completed on individuals who are referred or transferred from one (1) provider to another or referred or transferred within the same provider if the provider meets at least one (1) of the following conditions:

(I) The provider or component initiating the referral or transfer forwards a copy of the psychosocial assessment information prior to the arrival of the individual;

(II) Individuals are referred or transferred directly from a specific level of care to a lower or higher level of care (e.g., from detoxification to residential treatment or outpatient to residential treatment) within the same provider or from one (1) provider to another; or

(III) The individual is referred or transferred directly to the same level of care (e.g., residential level 1 to residential level 1) either within the same provider or from one (1) provider to another.

b. In the case of referral or transfer from one (1) provider to another, a referral or transfer is considered direct if it was arranged by the referring or transferring provider and the individual is subsequently placed with the provider within seven (7) calendar days of discharge. This does not preclude the provider from conducting an assessment. The following are further requirements related to referrals or transfers:

(I) If the content of a forwarded psychosocial does not comply with the psychosocial requirements of this rule, the information will be updated, or a new assessment will be completed;

(II) If an individual is placed with the receiving provider later than seven (7) calendar days following discharge from the provider that initiated the referral or transfer, but within 180 calendar days, the qualified professional of the receiving provider will

determine the extent of the update needed; and

(III) If an individual is placed with the receiving provider more than 180 calendar days after discharge from the provider that initiated the referral or transfer, a new psychosocial assessment must be completed.

(c) Co-occurring Mental Illness and Other Needs. The assessment process shall include the identification of individuals with mental illness and other needs. Such individual shall be accommodated directly or through referral. A record of all services provided directly or through referral shall be maintained in the individual's clinical record.

Rulemaking Authority 397.321(5) FS. Law Implemented 397.4014, 397.410 FS. History—New 8-29-19.

65D-30.0043 Placement.

(1) Criteria and Operating Procedures. This requirement applies to addictions receiving facilities, inpatient and outpatient detoxification, intensive inpatient treatment, residential treatment, day or night treatment with community housing, day or night treatment, outpatient treatment, intervention, intensive outpatient, and methadone medication-assisted treatment for opioid addiction. Providers shall have operating procedures that clearly state the criteria for admitting, retaining, transferring, and discharging individuals. This includes procedures for implementing these placement requirements.

(2) Individuals must be assessed prior to admission to a service component to determine level of service need and choice of the individual. If the provider completing the assessment does not offer the service needed, the provider must refer the individual to the assessed level of care.

(3) Primary Counselor, Orientation, and Initial Treatment Plan. This requirement applies to addictions receiving facilities, detoxification, intensive inpatient treatment, residential treatment, day or night treatment with community housing, day or night treatment, intensive outpatient treatment, outpatient treatment, and methadone medication-assisted treatment for opioid addiction.

(a) Primary Counselor. A primary counselor shall be assigned to each individual placed in a component. This standard does not apply to detoxification and addictions receiving facilities.

(b) Orientation. Each individual served must receive an orientation to the program at the time of admission and upon request. The orientation shall be in a language the individual or his or her representative understands. The individual's acknowledgement of the orientation and receipt of required information must be documented in the clinical record. The orientation shall include:

1. A description of services to be provided;
2. A copy of the individual's rights pursuant to Chapter 397, Part III, F.S.;
3. A summary of the facility's admission and discharge policies;
4. A copy of the service fee schedule, financial responsibility policy, and applicable fees;
5. Written rules of conduct for individual's served which shall be reviewed, signed, and dated;
6. A copy of the grievance process and procedure;
7. General information about infection control policies and procedures;
8. Limits of confidentiality;
9. Information on parental or legal guardian's access to information and participation in treatment; and
10. Information regarding advance directives which delineate the facility's position with respect to the state law and rules relative to advance directives.

(c) Individuals may not be retained in a facility when they require services beyond those for which the facility is licensed or has the functional ability to provide, as determined by the Medical Director in consultation with the facility chief executive officer or designee.

(4) Transfer and Discharge. Providers must ensure safe and orderly transfers and discharges in accordance with the facility's policies and procedures and in compliance with 42 CFR Part 2.

(a) Inpatient and residential providers shall not discharge an individual prior to treatment completion based on inability to pay. With consent of the individual, the provider may transfer the individual to a state-funded provider with capacity to accept and treat the individual.

(b) Inpatient and residential facilities must provide individuals and their guardians a minimum of 72 hours' notice of proposed transfer or discharge, except, in the following circumstances, the facility shall give notice as soon as practicable before the transfer or discharge:

1. The transfer or discharge is necessary for the individual's welfare and the individual's needs cannot be met by the facility, and the circumstances are documented in the individual's clinical record;

2. The health or safety of other program participants or facility staff would be endangered, and the circumstances are documented in the individual's clinical record; or
3. The individual leaves against medical advice.

Rulemaking Authority 397.321(5) FS. Law Implemented 397.321, 397.410 FS. History—New 8-29-19.

65D-30.0044 Plans, Progress Notes, and Summaries.

(1) Treatment Plan, Treatment Plan Reviews, and Progress Notes.

(a) Treatment Plan. Each individual shall be afforded the opportunity to participate and be actively engaged in the development and subsequent review of the treatment plan. The treatment plan shall include goals and related measurable behavioral objectives to be achieved by the individual, the tasks involved in achieving those objectives, the type and frequency of services to be provided, and the expected dates of completion. The treatment plan shall be signed and dated by the person providing the service and by the individual. If the treatment plan is completed by other than a qualified professional, the treatment plan shall be reviewed, countersigned, and dated by a qualified professional within 10 calendar days of completion. In the case of Inmate Substance Abuse Programs operated by or under contract with the Department of Corrections, or the Department of Management Services, the treatment plan shall be reviewed, countersigned, and dated by a qualified professional within 30 calendar days of completion. A written treatment plan shall be completed on each individual.

1. For long-term outpatient methadone detoxification and methadone medication-assisted treatment for opioid addiction, the treatment plan shall be completed prior to or within 30 calendar days of placement.

2. For intensive inpatient treatment, the treatment plan shall be completed within three (3) calendar days of placement.

3. For residential treatment level 1, the treatment plan shall be completed prior to, or within seven (7) calendar days of placement.

4. For residential treatment levels 2, 3, and 4 day or night treatment with community housing, the treatment plan shall be completed prior to or within 15 calendar days of placement.

5. For day or night treatment, the treatment plan shall be completed prior to or within 10 calendar days of placement.

6. For intensive outpatient treatment and outpatient treatment, the treatment plan shall be completed prior to or within 30 calendar days of placement.

7. For detoxification and addictions receiving facilities, an abbreviated treatment plan, as defined in subsection 65D-30.002(1), F.A.C., shall be completed upon placement. The abbreviated treatment plan shall contain a medical plan for stabilization and detoxification, provision for education, therapeutic activities and discharge planning, and in the case of addictions receiving facilities, a psychosocial assessment.

8. For providers that are licensed for multiple program components and deliver a continuum of care, any change in level of care requires a treatment plan review or treatment plan update.

(b) Treatment Plan Reviews. Treatment plan reviews shall be completed with each individual and shall be signed and dated by the individual within 30 calendar days of the completion of the treatment plan. The treatment plan must be reviewed when clinical changes occur and as specified in subparagraphs 65D-30.0044(1)(b)1.-4., F.A.C.

1. For intensive inpatient treatment, treatment plan reviews shall be completed every seven (7) calendar days.

2. For residential treatment levels 1, 2, and 3, day or night treatment with community housing, day or night treatment, and intensive outpatient treatment, treatment plan reviews shall be completed every 30 calendar days.

3. For residential treatment level 4, treatment plan reviews shall be completed every 90 calendar days.

4. For methadone medication-assisted treatment for opioid addiction and long-term outpatient methadone detoxification, treatment plan reviews shall be completed every 90 calendar days for the first year and every 6 months thereafter.

5. For outpatient treatment, treatment plan reviews shall be completed every 90 calendar days for the first year and every six (6) months thereafter.

For all components, if the treatment plan reviews are not completed by a qualified professional, the review shall be countersigned and dated by a qualified professional within five calendar days of the review.

For all components, if the treatment plan reviews are not completed by a qualified professional, the review shall be countersigned and dated by a qualified professional within five calendar days of the review.

(c) Progress Notes. Progress notes shall be entered into the clinical record documenting an individual's progress or lack of progress toward meeting treatment plan goals and objectives. When a single service event is documented, the progress note must be

signed and dated by the person providing the service and shall include the credentials of the person who signed the notes. When more than one (1) service event is documented, progress notes may be signed by any clinical staff member assigned to the individual. The following are requirements for recording progress notes:

1. For addictions receiving facilities, inpatient detoxification, outpatient detoxification, short-term residential methadone detoxification, short-term outpatient methadone detoxification, and intensive inpatient treatment, progress notes shall be recorded and signed at least daily;

2. For residential treatment, day or night treatment with community housing, day or night treatment, and long-term outpatient methadone detoxification, progress notes shall be recorded at least weekly;

3. For intensive outpatient treatment and outpatient treatment, progress notes shall be recorded at least weekly or, if contact occurs less than weekly, notes will be recorded according to the frequency of sessions; and

4. For methadone medication-assisted treatment for opioid addiction, progress notes shall be recorded according to the frequency of sessions and signed.

(2) Ancillary Services. This requirement applies to addictions receiving facilities, detoxification, intensive inpatient treatment, residential treatment, day or night treatment with community housing, day or night treatment, intensive outpatient treatment, outpatient treatment, aftercare, and medication-assisted treatment for opioid addiction. Ancillary services shall be provided directly or through referral in instances where a provider cannot or does not provide certain services needed by an individual. The provision of ancillary services shall be based on individual needs as determined by the treatment plan and treatment plan reviews. In cases where individuals need to be referred for services, the provider shall use a case management approach by linking individuals to needed services and following-up on referrals. All such referrals shall be initiated and coordinated by the individual's primary counselor or other designated clinical staff who shall serve as the individual's case manager. A record of all such referrals for ancillary services shall be maintained in the clinical record, including whether or not a linkage occurred or documentation of efforts to confirm a linkage when confirmation was not received.

(3) Prevention Plan, Intervention Plan, and Summary Notes.

(a) Prevention Plan. For individuals receiving indicated prevention services as described in paragraph 65E-14.021(4)(v), F.A.C., a prevention plan shall be completed within 45 calendar days. Prevention plans shall include goals and objectives designed to reduce risk factors and enhance protective factors. The prevention plan shall be reviewed and updated every 60 calendar days from the date of completion of the plan. The prevention plan shall be signed and dated by staff who developed the plan and signed and dated by the individual.

(b) Intervention Plan. For individuals involved in intervention on a continuing basis, an intervention plan shall be completed within 45 calendar days. Intervention plans shall include goals and objectives designed to reduce the severity and intensity of factors associated with the onset or progression of substance use. The intervention plan shall be reviewed and updated at least every 60 days. The intervention plan shall be signed and dated by staff who developed the plan and signed and dated by the individual.

(c) Summary Notes. Summary notes shall be completed in indicated prevention and intervention services where clinical records are required. Summary notes shall contain information regarding an individual's progress or lack of progress in meeting the conditions of the prevention or intervention plan described in paragraphs (a) and (b). Summary notes shall be entered into the individual's clinical record at least weekly for those weeks in which services are scheduled. Each summary note shall be signed and dated by staff delivering the service.

(4) Discharge and Transfer Summaries. This requirement applies to addictions receiving facilities, detoxification, intensive inpatient treatment, residential treatment, day or night treatment with community housing, day or night treatment, intensive outpatient treatment, outpatient treatment, medication-assisted treatment for opioid addiction, aftercare, and intervention.

(a) Discharge Summary. A written discharge summary shall be completed for individuals who complete services or who leave prior to completion of services. The discharge summary shall include a summary of the individual's involvement in services, the reasons for discharge, and the provision of and referral to other services needed by the individual following discharge, including aftercare. The discharge summary shall be completed within 15 business days and signed and dated by a primary counselor.

(b) Transfer Summary. A transfer summary in accordance with policies and procedures shall be completed immediately for individuals who transfer from one (1) component to another within the same provider and shall be completed within 5 calendar days when transferring from one (1) provider to another. In all cases, an entry shall be made in the individual's clinical record regarding the circumstances surrounding the transfer and that entry and transfer summary shall be signed and dated by a primary counselor within 15 days.

65D-30.0045 Rights of Individuals.

(1) Individual Rights. Individuals applying for or receiving services for substance use disorders are guaranteed the protection of fundamental human, civil, constitutional, and statutory rights, including those specified in Sections 397.501(1)-(10), F.S.

(a) Provisions. Basic individual rights shall include:

1. Provisions for informing the individual, family member, or authorized guardian of their rights and responsibilities, assisting in the exercise of those rights, and an accessible grievance system for resolution of conflicts;
2. Provisions assuring that a grievance may be filed for any reason with cause;
3. The prominent posting of notices informing individuals of the grievance system;
4. Access to grievance submission forms;
5. Education of staff in the importance of the grievance system and individual rights;
6. Specific levels of appeal with corresponding time frames for resolution;
7. Timely receipt of a filed grievance;
8. The logging and tracking of filed grievances until resolved or concluded by actions of the provider's governing board;
9. Written notification of the decision to the appellant; and
10. Analysis of trends to identify opportunities for improvement.

(b) Providing Information to Affected Parties. Notification to all parties of these rights shall include affirmation of an organizational non-relationship policy that protects a party's right to file a grievance or express their opinion and invokes applicability of state and federal protections. Providers shall post the number of the abuse hotline, Disability Rights Florida, and the regional Office of Substance Abuse and Mental Health in a conspicuous place within each facility and provide a copy to each individual receiving services.

(c) Implementation of Individual Rights Requirements by Department of Corrections and Department of Management Services. In lieu of the requirements of this subsection, the rights of individuals in Substance Abuse Programs:

1. Operated by the Department of Corrections shall be protected by the policies and procedures established by the Department of Corrections.
2. Under contract with the Department of Management Services shall be protected by the terms of the contract.

(2) Individual Employment. Providers shall ensure that all work performed on behalf of the provider by an individual receiving services is voluntary, justified by the treatment plan, and that all wages, if any, are in accordance with applicable wage and disability laws and regulations.

65D-30.0046 Staff Training, Qualifications, and Scope of Practice.

(1) Staff Training. Providers shall develop and implement a staff development plan. At least one (1) staff member with skill in developing staff training plans shall be assigned the responsibility of ensuring that staff development activities are implemented.

(a) The staff development plan must be reviewed at least annually through the quality assurance program and revised as needed. The plan must be signed and dated.

(b) All required training activities shall be documented and accessible for Department review, including the date, duration, topic, name(s) of participants, and name(s) of the trainer or training organization.

(c) New staff orientation. Within six (6) months of the hiring date, employees must complete the following trainings:

1. A two (2) hour educational course on HIV/AIDS as required by Section 381.0035, F.S.
2. Overdose prevention training which must be renewed biennially. The training shall include, at a minimum, information about:
 - a. Risk factors for overdose;
 - b. Overdose recognition and response; and
 - c. Naloxone, the medication that reverses opioid overdose, including how to use Naloxone and the importance of individuals at risk of opioid overdose and their friends and family having access to Naloxone.

3. Training in incident reporting procedures and requirements in accordance with subsection 65D-30.004(17), F.A.C., the affirmative duty requirements and protections of Chapter 415, F.S., and Title V of the Americans with Disabilities Act.

4. For direct care staff working in component services identified in subsection 65D-30.004(12), F.A.C., two (2) hours of

training in verbal de-escalation techniques and two (2) hours annually thereafter.

5. Staff performing nursing support functions must be trained in those services prior to performing that function.

6. For all direct care staff, training and certification in cardiopulmonary resuscitation (CPR) and first aid. Staff must maintain CPR and first aid certification, and a copy of the valid certificate must be filed in the personnel record.

(d) General Training Requirements. All staff and volunteers who provide direct care or prevention services shall participate in a minimum of 10 hours of documented training per year related to their duties and responsibilities. This includes training conducted annually in the following areas:

1. Prevention and control of infection in inpatient and residential settings;

2. Fire prevention, life safety, and disaster preparedness;

3. Safety awareness program;

4. Rights of individuals served;

5. Federal law, 42 CFR, Part 2, and Sections 397.334(10), 397.501(7), 397.752, F.S. applicable state laws regarding confidentiality.

(e) In instances where an individual has received the requisite training as required in paragraphs (1)(c) and (d) during the year prior to employment by a provider, that individual will have met the training requirements. This provision applies only if the individual is able to produce documentation that the training was completed and that such training was provided by persons who or organizations that are qualified to provide such training

(f) Special Training Requirements for Clinical Staff. All new clinical staff who work at least 20 hours per week or more must receive 12 hours of competency-based training related to substance use disorder treatment and recovery within the first year.

(g) Special Training Requirements for Prevention. In addition to paragraphs (1)(c) and (d), new staff providing prevention services shall receive 12 hours basic training in science-based prevention within the first year of employment.

(h) Medication Administration Training Requirements. Training is required before personnel may supervise the self-administration of medication. At least two and a half (2.5) hours of training is required which may be conducted only by licensed practical nurses, licensed registered nurses or advanced practice registered nurses. Personnel responsible for training must certify by signed document or certificate the competency of unlicensed staff to supervise the self-administration of medication. Proof of training shall be documented in the personnel file and shall be completed prior to implementing the supervision of self-administration of medication.

(i) In addition to the requirements of paragraph (h), self-administration of medication training must include step-by-step procedures, covering, at a minimum, the following subjects:

1. Safe storage, handling, and disposal of medications;

2. Comprehensive understanding of and compliance with medication instructions on a prescription label, a healthcare practitioner's order, and proper completion of medication observation record (MOR) form;

3. The medical indications and purposes for commonly used medications, their common side effects, and symptoms of adverse reactions;

4. The proper administration of oral, transdermal, ophthalmic, otic, rectal, inhaled or topical medications;

5. Safety and sanitation practices while administering medication;

6. Medication administration documentation and record keeping requirements;

7. Medical errors and medical error reporting;

8. Determinations of need for medication administration assistance and informed consent requirements;

9. Procedural arrangements for individuals who require medication offsite; and

10. Validation requirements.

(2) Clinical Supervision. A qualified professional shall supervise clinical services, as permitted within the scope of their qualifications. In addition, all licensed and unlicensed staff shall be supervised by a qualified professional. In the case of medical services, medical staff may provide supervision within the scope of their license. Supervisors shall conduct regular reviews of work performed by subordinate employees. Clinical supervision may include supervisory participation in treatment planning meetings, staff meetings, observation of group sessions and private feedback sessions with personnel. The date, duration, and content of supervisory sessions shall be clearly documented for staff in each licensed component and made available for Department review.

(3) Scope of Practice. Staff not licensed under Chapter 458, 459, 464, 490 or 491, F.S., providing services specific to substance use are limited to the following tasks unless otherwise specified in this rule:

- (a) Screening;
- (b) Psychosocial assessment;
- (c) Treatment planning;
- (d) Referral;
- (e) Service coordination;
- (f) Consultation;
- (g) Continuing assessment and treatment plan reviews;
- (h) Recovery support services;
- (i) Crisis intervention;
- (j) Individual, family, and community education;
- (k) Documentation of progress;
- (l) Any other tasks permitted in these rules and appropriate to that licensable component; and
- (m) Counseling, including;
 1. Individual counseling;
 2. Group counseling; and
 3. Counseling with families, couples, and significant others.
- (4) Staff Qualifications. Staff must provide services within the scope of their professional licensure certification; or training and competence in applicable clinical protocols.

(a) The scope of practice limitations listed in subsection (3) apply to the following unlicensed staff who must work directly under the supervision of a qualified professional:

1. Bachelor's or master's degree level practitioners. Practitioners must hold a degree from an accredited university or college with a major in counseling, social work, psychology, nursing, rehabilitation, special education, health education, or a related human services field;
2. Registered marriage and family therapy, clinical social work, and mental health counseling interns;
3. Certified master's degree level addiction professionals who are certified by the Florida Certification Board;
4. Certified addictions professionals who are certified by the Florida Certification Board;
5. Certified addiction counselors who are certified by the Florida Certification Board.

(b) Certified recovery peer specialists and specialist or certified recovery support specialists who are certified by the Florida Certification Board may provide all services listed in subsection (3) of this rule, except counseling listed in paragraph (3)(l), under the supervision of a qualified professional or a certified recovery peer specialist with a minimum of three (3) years of experience providing recovery support services to individuals with substance use disorders. Recovery support specialists and recovery peer specialists are allowed one year from the date of their employment to obtain certification through the Florida Certification Board.

Rulemaking Authority 397.321(5) FS. Law Implemented 397.321, 397.410 FS. History—New 8-29-19.

65D-30.0047 Facility Standards.

Facility standards in subsections (1)-(11) below apply to addictions receiving facilities, inpatient detoxification facilities, intensive inpatient treatment, and residential treatment facilities. Facility standards in subsections (6)-(11) apply to outpatient detoxification, day or night treatment with community housing, day or night treatment, intensive outpatient treatment, outpatient treatment, and methadone medication-assisted treatment for opioid addiction.

(1) Grounds. Each facility and its grounds shall be designed to meet the needs of the individuals served, the service objectives, and the needs of staff and visitors. Providers shall afford each individual access to the outdoors. Access may be restricted in cases where the individual presents a clear and present danger to self or others or is at risk for elopement.

(2) Space and Equipment. Provisions shall be made to ensure that adequate space and equipment are available for all of the service components of the facility, and the various functions within the facility.

(3) Personal Possessions. Provisions shall be made which will ensure that individuals have access to individual storage areas for clothing and personal possessions.

(4) Laundry Facilities. Laundry facilities or laundry services shall be available which ensure the availability of clean clothing, bed linens, and towels.

(5) Personal Hygiene. Items of personal hygiene shall be provided if the individual is unable to provide these items.

(6) Safety. Providers shall ensure the safety of individuals receiving services, staff, visitors, and the community to the extent allowable by law.

(7) Managing Disasters. Providers shall have written disaster preparedness plans as outlined in paragraph 65E-12.106(12)(a), F.A.C. In addition, the plan shall include procedures for the transfer of any individuals to other providers. In the cases of emergency temporary relocation, a provider must deliver or arrange for appropriate care and services to all individuals. All such plans shall be provided to the regional office upon request. The chief executive officer shall review, sign and date the plan at least annually.

(8) Housekeeping and Maintenance. Provisions shall be made to ensure that housekeeping and maintenance services are capable of keeping the building and equipment clean and in good repair.

(9) Hazardous Conditions. Buildings, grounds, equipment, and supplies shall be maintained, repaired, and cleaned so that they are not hazardous to the health and safety of individuals receiving services, staff, or visitors.

(10) Hazardous Materials. Providers shall ensure that hazardous materials are properly identified, handled, stored, used, and dispensed.

(11) Compliance with Local Codes. All licensed facilities used by a provider, including community housing, shall comply with local fire safety standards enforced by the State Fire Marshal, pursuant to Section 633.104, F.S., rules established pursuant to rule Chapter 69A-44, F.A.C., and with health and zoning codes enforced at the local level. Providers shall update and have proof of compliance with local fire and safety and health inspections annually for applicable components. (Inmate Substance Abuse Programs operated by or under contract with the Department of Corrections or the Department of Management Services, and Juvenile Justice Commitment Programs and detention facilities operated by or under contract with the Department of Juvenile Justice are exempt from this requirement.)

Rulemaking Authority 397.321(5) FS. Law Implemented 397.321, 397.410 FS. History—New 8-29-19.

65D-30.0048 Offender Referrals Under Chapter 397, F.S.

(1) Authority to Refer. Any offender, including any minor, who is charged with or convicted of a crime, is eligible for referral to a provider. The referral may be from the court or from the criminal or juvenile justice authority which has jurisdiction over that offender, and may occur prior to, in lieu of, or in addition to, final adjudication, imposition of penalty or sentence, or other action.

(2) Referral Information. Referrals shall be in writing and signed by the referral source.

(3) Provider Responsibilities.

(a) If the offender is not appropriate for placement by the provider, this decision must immediately be communicated to the referral source and documented in writing within 24 hours, stating reasons for refusal.

(b) The provider, after consultation with the referral source, may discharge the offender to the referral source.

(c) When an offender is successful or unsuccessful in completing treatment or when the commitment period expires, the provider shall communicate this to the referral source.

(4) Assessment of Juvenile Offenders.

(a) Each juvenile offender referred by the court and the Department of Juvenile Justice shall be assessed to determine the need for services for substance use disorders.

(b) The Department, in conjunction with the court and the Department of Juvenile Justice, shall establish procedures to ensure that juvenile offenders are assessed for substance use disorders and that diversion and adjudication proceedings include conditions and sanctions to address substance use disorders. These procedures must address:

1. Responsibility of local contracted providers for assessment;

2. The role of the court in handling non-compliant juvenile offenders; and

3. Priority Services.

4. Families of the juvenile offender may be required by the court to participate in the assessment process and other services under the authority found in Chapter 985, F.S.

Rulemaking Authority 397.321(5) FS. Law Implemented 397.321, 397.410, 397.4014 FS. History—New 8-29-19.

65D-30.0049 Voluntary and Involuntary Placement.

(1) Voluntary and Involuntary Placement Under Chapter 397, F.S., Parts IV and V.

(a) Eligibility Determination.

1. Voluntary Placement. To be considered eligible for treatment on a voluntary basis, an applicant for services must meet

diagnostic criteria for substance use disorders utilizing a validated tool used for service determination.

2. Involuntary Placement. To be considered eligible for services on an involuntary basis, a person must meet the criteria for involuntary placement as specified in Section 397.675, F.S.

(b) Provider Responsibilities Regarding Involuntary Placement.

1. Persons who are involuntarily placed shall be served only by licensed service providers as defined in Section 397.311(25), F.S., and only in those components permitted to admit individuals on an involuntary basis.

2. Providers which accept involuntary referrals must provide a description of the eligibility and diagnostic criteria and the placement process to be followed for each of the involuntary placement procedures described under Sections 397.677, 397.679, 397.6798, 397.6811 and 397.693, F.S.

3. Individuals shall be referred to more appropriate services if the provider determines that the person should not be placed or should be discharged. Such referral shall follow the requirements found in Sections 397.6751(2)(a), (b), (c) and (3)(a), (b), F.S. The decision to refuse to admit or to discharge shall be made by a qualified professional. Any attempts to contact the referral source must be made in accordance with Title 42, Code of Federal Regulations, Part 2.

4. In cases in which the court ordering involuntary treatment includes a requirement in the court order for notification of proposed release, the provider must notify the original referral source in writing. Such notification shall comply with legally defined conditions and timeframes and conform to confidentiality regulations found in Title 42, Code of Federal Regulations, Part 2, and Section 397.501(7), F.S.

(c) Assessment Standards for Involuntary Treatment Proceedings. Providers that make assessments available to the court regarding hearings for involuntary treatment must define the process used to complete the assessment. This includes specifying the protocol to be utilized, the format and content of the report to the court, and the internal procedures used to ensure that assessments are completed and submitted within legally specified timeframes. For persons assessed under an involuntary order, the provider shall address the means by which the physician's review and signature for involuntary assessment and stabilization and the signature of a qualified professional for involuntary assessments only, will be secured. This includes the process that will be used to notify affected parties stipulated in the petition.

(d) Provider Initiated Involuntary Admission Petitions. Providers are authorized to initiate petitions under the involuntary assessment and stabilization and involuntary treatment provisions when that provider has direct knowledge of the respondent's substance use disorder or when an extension of the involuntary admission period is needed. Providers shall specify the circumstances under which a petition will be initiated and the means by which petitions will be drafted, presented to the court, and monitored through the process. This shall be in accordance with Title 42, Code of Federal Regulations, Part 2. The forms to be utilized and the methods to be employed to ensure adherence to legal timeframes shall be included in the procedures.

(2) For persons with a co-occurring substance use and mental health disorders, providers shall develop and implement operating procedures for serving or arranging for services.

Rulemaking Authority 397.321(5) FS. Law Implemented 397.321, 397.501, 397.601, 397.675, 397.6751 FS. History—New 8-29-19.

65D-30.005 Standards for Addictions Receiving Facilities.

An addictions receiving facility is a secure, acute-care or sub-acute, residential facility operated 24 hours-per-day, 7 days-per-week, designated by the Department to serve individuals found to be substance use impaired as described in Section 397.675, F.S., and who meet the placement criteria for this component. In addition to Rule 65D-30.004, F.A.C., the following standards apply to addictions receiving facilities.

(1) Designation of Addictions Receiving Facilities. The Department shall designate addictions receiving facilities. The provider shall indicate on the licensure application for this service component that designation is requested. Once the designation request is received by the Regional Substance Abuse and Mental Health Program Office, the Regional Substance Abuse and Mental Health Program Director shall submit a written recommendation to the Office of Substance Abuse and Mental Health headquarters in Tallahassee, Florida. The headquarters Director of Substance Abuse and Mental Health may approve or deny the request and shall respond in writing to the Chief Executive Officer of the requesting provider.

(a) Criteria for Department approval of addictions receiving facility designation:

1. The Department ensures provider's policies and procedures achieve at least 80 percent compliance with applicable licensing standards; and

2. The Department assesses that the provider is capable of providing a secure, acute care facility to include compliance with

seclusion and restraint; and

3. A Regional Substance Abuse and Mental Health Director recommends in writing that the Department designate the provider's facility as a designated addictions receiving facility.

(b) If the request is denied, the response shall specify the reasons for the denial. If the request is approved, the response shall include a certificate designating the facility. The designation shall be valid for as long as the provider's license for the addiction receiving facility is valid.

(2) Services.

(a) Stabilization and Detoxification. Following the nursing physical screen, and in cases where medical emergency services are unnecessary, the individual shall be stabilized in accordance with their presenting condition. Detoxification shall be initiated if this course of action is determined to be necessary.

(b) Supportive Counseling. Each individual shall be offered supportive counseling on a daily basis, unless an individual is not sufficiently stabilized as defined in subsection 65D-30.002(78), F.A.C. Supportive counseling sessions shall be of sufficient duration to enable staff to make reasonable decisions regarding the individual's need for other services. Services shall be directed toward assuring the individual's most immediate needs are addressed and that the individual is encouraged to remain engaged in treatment and to follow up on referrals after discharge.

(c) Daily Schedule. The provider shall develop a daily schedule that shall be posted in clear view of all program participants and include recreational and educational activities. Participation in daily activities by the individual shall be documented in the individual's clinical record.

(3) Facility Requirements Related to Screening and Assessment. Providers shall designate an area of the facility that is properly equipped and furnished for conducting screening and assessment. The area shall be conducive to privacy and freedom from distraction, and shall be accessible to transportation, including law enforcement vehicles and ambulances.

(4) Observation of Individuals. Individuals requiring close medical observation, as determined by medical staff, shall be visible and readily accessible to the nursing staff 24 hours per day and 7 days per week. Staff shall perform visual checks minimally every 15 minutes, which shall be documented in the individual's clinical record. Individuals who do not require close medical observation shall be in a bed area that allows for general nursing observation.

(5) Eligibility Criteria. To be considered eligible for placement, a person must be unable to be placed in another component and must also fall into one (1) of the following categories:

(a) An individual who presents for voluntary admission who displays behaviors that indicate potential harm to self or others due to a substance use issue or who meets diagnostic or medical criteria justifying admission in a secure facility; or

(b) An individual who meets the criteria for involuntary admission specified in Section 397.675, F.S., or

(c) An adult or juvenile offender who is ordered for assessment or treatment under Sections 397.705 and 397.706, F.S., and who meets diagnostic or medical criteria justifying placement in an addictions receiving facility, or

(d) Juveniles found in contempt as authorized under Section 985.037, F.S.

(6) Exclusionary Criteria for Addictions Receiving Facilities. Persons ineligible for placement include:

(a) Persons found not to be using substances or whose substance use is at a level which permits them to be served in another component, with the exception of persons placed for purposes of securing an assessment for the court; and

(b) Persons found to be beyond the safe management capability of the provider as defined under Section 397.311(3), F.S., and as described under Section 397.6751(1)(f), F.S.

(7) Admission Procedures. Following the nursing physical screen, the individual shall be screened to determine eligibility for admission. The decision to admit or not to admit shall be made by a physician, a qualified professional, or an R.N., and shall be based upon the results of screening information and face-to-face consultation with the person to be admitted.

(8) Notification and Referral. In the event that the addictions receiving facility has reached full capacity or it has been determined that the screened individual cannot be safely managed, the provider shall attempt to notify the referral source and document the attempt. In addition, the provider shall provide assistance in referring the person to another component, in accordance with Section 397.6751, F.S.

(9) Involuntary Assessment and Disposition.

(a) Involuntary Assessment. An assessment shall be completed for each individual admitted to an addictions receiving facility under protective custody, emergency admission, alternative involuntary assessment for minors, and under involuntary assessment and stabilization. The assessment shall be completed by a qualified professional and based on the requirements in paragraph 65D-

30.0042(2)(b), F.A.C. The assessment shall be directed toward determining the individual’s need for additional treatment and the most appropriate services and supports.

(b) Disposition Regarding Involuntary Admissions. Within the assessment period, one (1) of the following actions shall be taken, based upon the needs of the individual and, in the case of a minor, after consultation with the parent(s) or guardian(s).

1. The individual shall be released and notice of the release shall be given to the applicant or petitioner and to the court, pursuant to Section 397.6758, F.S. In the case of a minor that has been assessed or treated through an involuntary admission, that minor must be released to the custody of his parent(s), legal guardian(s), or legal custodian(s).

2. The individual shall be asked if they will consent to voluntary treatment at the provider, or consent to be referred to another provider for voluntary treatment in another service component.

3. A petition for involuntary treatment will be initiated.

(10) Notice to Family or Legal Guardian. In the case of a minor, the minor’s parent(s) or legal guardian(s) shall be notified upon admission to the facility. Such notification shall be in compliance with the requirements of Title 42, Code of Federal Regulations, Part 2.

(11) Staffing. Providers shall conduct clinical and medical staffing of individuals admitted for services. Participation in staffing shall be dictated by the individual’s needs. At a minimum, staffing shall include participation by a physician, nurse, primary counselor, and the individual served unless clinically contraindicated.

(12) Staff Coverage. A physician, P.A., or A.R.N.P. shall make daily visits to the facility for the purpose of conducting physical examinations and addressing the medical needs of individuals. A full-time R.N. shall be the supervisor of all nursing services. An R.N. or L.P.N. shall be on-site 24 hours per day, 7 days per week. At least one (1) qualified professional shall be on staff and shall be a member of the treatment team. At least one (1) member of the clinical staff shall be available on-site for eight (8) hours daily and be on-call thereafter.

(13) Staffing Requirement and Bed Capacity. The staffing requirement for nurses and nursing support personnel for each shift shall consist of the following:

Licensed Bed Capacity	Nurses	Nursing Support
1-10	1	1
11-20	1	2
21-30	2	2

The number of nurses and nursing support staff shall increase in the same proportion as the pattern described above. In those instances where a provider operates a crisis stabilization unit and addictions receiving facility within the same facility, the combined components shall conform to the staffing requirement of the component with the most restrictive requirements.

(14) Seclusion and Restraint.

(a) Addictions receiving facilities may utilize seclusion and restraint. If seclusion or restraint is utilized, addictions receiving facilities shall adhere to all standards and requirements for seclusion and restraint as described in Rule 65E-5.180, F.A.C.

(b) If an addictions receiving facility chooses not to conduct any seclusions and restraints, the provider shall not maintain a seclusion and restraint room, and the provider’s policies and procedures shall prohibit staff from conducting seclusions and restraints.

(c) De-escalation techniques shall be employed before seclusion or restraint and in accordance with the provider’s policies and procedures. If seclusion or restraint is utilized, it shall be documented in the clinical record and reported using the Department’s web-based reporting system as described in Chapter 65E-5, F.A.C.

(d) Under no circumstances shall individuals being served be involved in the seclusion or restraint of other individuals. Additionally, seclusion, or restraint shall not be utilized as punishment or for the convenience of staff.

Rulemaking Authority 397.321(5) FS. Law Implemented 397.311(26), 397.321, 397.4014, 397.410 FS. History—New 5-25-00, Amended 4-3-03, 8-29-19.

65D-30.006 Standards for Detoxification.

In addition to Rule 65D-30.004, F.A.C., the following standards apply to detoxification.

(1) Detoxification is a process involving acute or subacute care that is provided on a non-hospital inpatient or an outpatient basis to assist individuals who meet the placement criteria for this component to withdraw from the physiological and psychological

effects of substance use.

(2) General Requirements. Detoxification protocols shall be developed by the medical director, or in accordance with the medical protocol established in subsection 65D-30.004(6), F.A.C., and implemented upon admission according to the physiological and psychological needs of the individual.

(3) Inpatient Detoxification.

(a) Services.

1. Stabilization. Stabilization services shall be provided as an initial phase of detoxification.

2. Supportive Counseling. Each individual shall participate in supportive counseling on a daily basis unless the individual is not sufficiently stable. Supportive counseling sessions shall be of sufficient duration to enable staff to make reasonable decisions regarding the individual's need for other services. Services shall be directed toward ensuring that the individual's most immediate needs are addressed and encouraging the individual to remain engaged in treatment and to follow up on referrals after discharge.

3. Daily Activities. The provider shall develop a schedule of daily activities that will be provided based on the detoxification protocols as defined in subsection 65D-30.002(27), F.A.C. This shall include recreational and educational activities, and participation shall be documented in the clinical record.

4. Involuntary Assessment and Disposition. Individuals who are involuntarily admitted into a detoxification unit under protective custody, emergency admission or involuntary assessment and stabilization pursuant to Section 397.6772, 397.6797 or 397.6811, F.S., shall be assessed and referred as in subsection 65D-30.005(9), F.A.C.

(b) Observation of Individuals. Individuals requiring close medical observation, as determined and documented by medical staff, shall be visible and readily accessible to nursing staff. Individuals who do not require close medical observation shall be in a bed area that allows for general nursing observation.

(c) Staff Coverage. Each facility shall have a physician on call at all times to address medical problems and to provide emergency medical services. The physician's name, telephone number, and schedule for this arrangement shall remain current and clearly posted at the nurse's station. An R.N. shall be the supervisor of all nursing services and shall be on-call 24 hours per day, 7 days per week. An L.P.N. or R.N. shall be on-site 24 hours per day, 7 days per week. All staff shall have immediate access to a nurse supervisor or physician for consultation.

(d) Staffing Requirement and Bed Capacity. The staffing requirement for nurses and nursing support personnel for each shift shall be as follows:

Licensed Bed Capacity	Nurses	Nursing Support
1-15	1	1
16-20	1	2
21-30	2	2

The number of nurses and nursing support staff shall increase in the same proportion as the requirement described above. In instances where an inpatient detoxification component and a licensed crisis stabilization unit are co-located, the staffing requirement for the combined components shall conform to the staffing requirement of the component with the more restrictive requirements.

(4) Outpatient Detoxification. The following standards apply to outpatient detoxification.

(a) Eligibility for Services. Eligibility for outpatient detoxification shall be determined from the following:

1. The individual's overall medical condition;

2. The individual's family or support system, for the purpose of observing the individual during the detoxification process, and for monitoring compliance with the medical protocol;

3. The individual's overall stability and behavioral condition;

4. The individual's ability to understand the importance of managing withdrawal utilizing medications and to comply with the medical protocol; and

5. An assessment of the individual's ability to abstain from the use of substances, except for the proper use of prescribed medication.

(b) Drug Screening. A drug and alcohol screen shall be conducted at admission. Thereafter, the program shall require random drug and alcohol screening for each individual in accordance with the provider's medical protocol.

(c) Services.

1. Supportive Counseling. Each individual shall participate in supportive counseling on a weekly basis. Counseling sessions

shall be of sufficient duration to enable staff to make decisions regarding the individual's need for other services and to determine progress.

2. Referral to Inpatient Detoxification. Providers shall refer individuals to inpatient detoxification or the appropriate level of care when there is evidence that the individual is unable to comply with the outpatient protocol.

(d) Staffing Requirement. Staffing for outpatient detoxification shall minimally consist of the following:

1. A physician, or an A.R.N.P. or a P.A. working under the supervision of a physician, available and on-call during operating hours,

2. An R.N., or an L.P.N. working under the supervision of an R.N., on-site during operating hours; and,

3. A counselor, on-site during operating hours.

(e) Training. All direct services staff working in outpatient detoxification shall be trained in the outpatient detoxification protocol prior to having contact with the individual in need of services.

(5) Additional Requirements for the Use of Methadone in Detoxification. In cases where a provider uses methadone in the detoxification protocol, the provider shall comply with the minimum standards found under subsection 65D-30.006(2), F.A.C., if methadone is provided as part of inpatient detoxification, and subsection 65D-30.006(3), F.A.C., if methadone is provided as part of outpatient detoxification. In either case, methadone may be used short-term (no more than 30 days) or long-term (no more than 180 days). Short-term detoxification is permitted on an inpatient and an outpatient basis while long-term detoxification is permitted on an outpatient basis only. A provider shall not admit an individual in more than two (2) detoxification episodes in one (1) year. The physician or other medically qualified professional designee identified in accordance with the medical protocol established in subsection 65D-30.004(7), F.A.C., shall assess the individual upon admission to determine the need for other forms of treatment. Providers shall also comply with the standards found under subsection 65D-30.014(4), F.A.C., with the exception of the following conditions:

(a) Take-home methadone is not allowed during short-term detoxification.

(b) Individuals involved in long-term detoxification shall have a drug screen initially and at least monthly thereafter.

(c) Individuals involved in short-term detoxification shall have at least one (1) initial drug screen.

(5) Hours of Operation. Providers shall post their hours of operation and this information shall be visible to the public.

Rulemaking Authority 397.321(5) FS. Law Implemented 397.311(26), 397.321, 397.4014, 397.410 FS. History—New 5-25-00, Amended 4-3-03, 8-29-19.

65D-30.0061 Standards for Intensive Inpatient Treatment.

(1) Intensive Inpatient Treatment includes a planned regimen of evaluation, observation, medical monitoring, and clinical protocols delivered through an interdisciplinary team approach provided 24 hours-per-day, 7 days per week in a hospital setting.

(2) Admission Criteria. Intensive inpatient treatment is appropriate for individuals whose acute biomedical, behavioral, cognitive, and emotional problems are severe enough to require primary medical and nursing care. These individuals may exhibit violent or suicidal behaviors, or other severe disturbances due to substance use. Program services may be offered in an appropriately licensed facility located in a community setting, a specialty unit in a general or psychiatric hospital, or other licensed health care facility. In addition to Rule 65D-30.004, F.A.C., the following standards apply to intensive inpatient treatment.

(3) Specialized Services. Providers shall make provisions to meet the needs of individuals with a co-occurring substance use and mental health disorder and related biomedical disorders. This includes protocols for:

(a) Providing clinical services by an interdisciplinary team of qualified staff daily;

(b) Planning clinical program activities designed to stabilize acute substance use and other psychiatric symptoms, adapted to the individual's developmental stage and level of comprehension;

(c) Monitoring the individual's compliance in taking prescription medication on a regular basis, including medication education;

(d) Reviewing the individual's recent psychiatric history and mental status examination;

(e) Developing a comprehensive psychiatric history and conducting a mental status examination as determined by the individual's needs;

(f) Providing co-occurring enhanced services utilizing best practices; and

(g) Providing related biomedical services, as determined by the individual's needs.

(4) Standard Services. Standard services shall include a specified number of hours of counseling as provided for in subsection 65D-30.0061(5), F.A.C. Each provider shall be capable of providing or arranging for the services listed below. With the exception of

counseling, it is not intended that all services listed below be provided. Services shall be provided in accordance with the needs of the individual as identified in the assessment and treatment plan as follows:

- (a) Individual counseling;
- (b) Group counseling;
- (c) Counseling with family members or members of the individual's support system;
- (d) Substance-related and recovery-focused education, such as strategies for avoiding substance use or relapse, information regarding health problems related to substance use, motivational enhancement, and strategies for achieving a substance-free lifestyle;
- (e) Life skills training, such as anger management, communication skills, employability skills, problem solving, relapse prevention, recovery management, decision-making, relationship skills, and symptom management;
- (f) Expressive therapies, such as recreation therapy, art therapy, music therapy, or dance (movement) therapy to provide the individual with alternative means of self-expression and problem resolution;
- (g) Training or provision of information regarding health and medical issues;
- (h) Employment or educational support services to assist individuals in becoming financially independent; and
- (i) Mental health services for the purpose of:
 - 1. Managing individuals with disorders who are stabilized;
 - 2. Evaluating individuals' needs for in-depth mental health assessment;
 - 3. Training individuals to manage symptoms; and
 - 4. If the provider is not staffed to address primary mental health problems which may arise during treatment, the provider should initiate a timely referral to an appropriate provider for mental health crises or for the emergence of a primary mental health disorder in accordance with the provider's policies and procedures.

(4) Required Hours of Services. Individuals shall receive services each week in accordance with subsections 65D-30.0061(2) and (3), F.A.C., including at least 14 hours of counseling and 20 hours of other structured activities.

(5) Observation of Individuals. Individuals requiring close medical observation, as determined and documented by medical staff, shall be visible and readily accessible to nursing staff. Individuals who do not require close medical observation shall be in a bed area that allows for general nursing observation.

(6) Staff Coverage.

(a) There shall be nursing coverage 24 hours per day, 7 days per week. An R.N. shall supervise all nursing staff and an R.N. or L.P.N. shall be on-site. Nursing staff shall be responsible for monitoring each individual's medical progress and medication administration. An R.N. or L.P.N. shall conduct a mental health focused nursing assessment at the time of admission. A physician shall be on-call 24 hours per day, 7 days per week.

(b) A psychiatrist or psychiatric A.R.N.P. or P.A. shall be available by telephone to assess the individual's mental condition, if needed. A face-to-face assessment shall be conducted on individuals with a co-occurring disorder within three (3) calendar days of admission.

(c) A qualified professional licensed under Chapter 490 or 491, F.S., shall be a member of the interdisciplinary team and shall be on-site daily. At least one (1) member of the non-medical clinical staff shall be on-site for eight (8) hours daily and be on-call thereafter.

(7) Caseload. No primary counselor may have a caseload that exceeds 10 currently participating individuals.

(8) Transportation. Each provider shall arrange for or provide transportation services to individuals who are involved in activities or in need of services that are provided at other facilities.

Rulemaking Authority 397.321(5) FS. Law Implemented 397.321(1), 397.4103 FS. History—New 12-12-05, Amended 8-29-19.

65D-30.007 Standards for Residential Treatment.

In addition to Rule 65D-30.004, F.A.C., the following standards apply to residential treatment.

(1) Residential treatment is a service provided in a structured and supervised live-in environment within a nonhospital or free-standing setting 24 hours-per-day, 7 days-per-week, and is intended for individuals who meet the placement criteria for this component. For the purpose of these rules, there are four (4) levels of residential treatment that vary according to the type, frequency, and duration of services provided.

(2) Facilities Not Required to be Licensed as Residential Treatment. Licensure as residential treatment, as defined in paragraph

65D-30.002(16)(d), F.A.C., shall not apply to facilities that only provide housing, meals, or housing and meals to individuals who are substance use impaired or in recovery. These facilities do not provide clinical services; however, they may arrange for or provide support groups such as Alcoholics Anonymous and Narcotics Anonymous. All other facilities providing services to individuals as described in subsections 65D-30.007(2) and (3), F.A.C., either at the facility or at alternate locations, must be licensed under this rule.

(3) Levels of Residential Treatment. For the purpose of this rule, there are four levels of residential treatment. In each level, treatment shall be structured to serve individuals who need a safe and stable living environment in order to develop sufficient recovery skills for the transition to a less restrictive level of care or reintegration into the general community in accordance with placement criteria. Treatment shall also include a schedule of services provided within a positive environment that reinforce the resident's recovery. Individuals will be placed in a level of residential treatment that is based upon their treatment needs and circumstances. Because treatment plans should be specific to the individual, length of stay and duration of treatment shall be dependent upon the individual's: a) severity of illness or disorder, b) level of functioning, and c) clinical progress in treatment and outcomes based on individualized treatment goals for all levels of residential treatment.

(a) Level 1 programs offer organized treatment services that feature a planned and structured regimen of care in a 24-hour residential setting. These programs are more than a 24-hour supported living environment (like those in level 4), and are a 24-hour treatment setting. There are two (2) categories of treatment under this level of care.

1. Adult Level 1 programs are appropriate for adults age 18 years and older with a substance use disorder or a co-occurring mental health and substance use disorder who have sub-acute biomedical, behavioral, emotional, or cognitive conditions severe enough that they require treatment in a Level 1 program, but do not need the full resources of an acute care general hospital or a medically managed inpatient treatment program. This level includes programs that provide services on a short-term basis. The emphasis is on an intensive regimen of clinical services using a multidisciplinary team approach. Services may include some medical services based on the needs of the individual.

2. Adolescent Level 1 programs are appropriate for adolescents under the age of 18 years with a substance use disorder or who have a co-occurring substance use and mental health disorders or symptoms. This level is often necessary to help change negative patterns of behavior, thinking, and feeling that predispose one to substance use and to develop skills to maintain a substance-free life. Services should take into account the different developmental needs based on the age of the adolescent and address any deficits in behavioral, cognitive, and social-emotional development often associated with substance use during the adolescent period. Seventeen-year-olds who turn 18 while completing treatment shall be allowed to stay only if it is clinically indicated, there is one-on-one supervision, and they have separate bedrooms.

(b) Level 2 programs are structured rehabilitation-oriented group facilities that serve persons with a substance use disorder or a co-occurring mental health and substance use disorder who have significant deficits in independent living skills and need extensive support and supervision. Programs include those referred to as therapeutic communities or some variation of therapeutic communities and are longer term than Level 1. There are two (2) categories of treatment under this level of care.

1. Adult Level 2 programs are appropriate for adults age 18 years and older with a substance use disorder or a co-occurring mental health and substance use disorder who have multi-dimensional needs of such severity that they cannot safely be treated in less intensive levels of care. This level is appropriate for adults who may experience significant social and psychological deficits, such as chaotic, and often abusive, interpersonal relationships; criminal justice involvement; prior treatment in less restrictive levels of care; inconsistent work histories and educational experiences; homelessness or inadequate housing; or anti-social behavior. In addition to clinical services, considerable emphasis is placed on services that address the individual's educational and vocational needs, socially dysfunctional behavior, and need for stable housing upon discharge. It also includes services that promote continued abstinence from substance use upon the individual's return to the community.

2. Adolescent Level 2 programs are appropriate for adolescents under the age of 18 with a substance use disorder or a co-occurring mental health and substance use disorder who have impaired functioning across a comprehensive range of psychosocial domains. This is characterized as having unpredictable fluctuations in mood, and developmental or cognitive difficulties related to mental health symptoms or disorders. In addition to providing clinical services, as defined in Rule 65D-30.002, F.A.C., this level of care provides services to improve interpersonal relationships, conflict resolution skills, impulse control problems and to reduce social inhibition or withdrawal. For these adolescents, treatment must occur in a structured environment conducive to teaching and practicing prosocial behavior to facilitate healthy reintegration into the community.

(c) Level 3 programs are appropriate for adults age 18 years and older with a substance use disorder or a co-occurring mental

health and substance use disorder whose cognitive functioning has been severely impaired from the chronic use of substances, either temporarily or permanently. This would include individuals who have varying degrees of organic brain disorder or brain injury or other problems that require extended care. The emphasis is on providing services that work on cognitive problems and activities of daily living, socialization, and specific skills to restore and maintain independent living. Typically, services are slower paced, more concrete and repetitive. This level excludes adolescent programs.

(d) Level 4 programs are appropriate for adults or adolescents with a substance use disorder or a co-occurring mental health and substance abuse use disorder and provide services on a short-term basis. This level is appropriate for individuals who have completed other levels of residential treatment, particularly levels 2 and 3. This includes individuals who have functional limitations in application of recovery skills, self-efficacy, or a lack of connection to the community systems of work, education, or family life. Although clinical services are provided, the emphasis is on services that are low-intensity and emphasize a supportive environment. This includes services that focus on recovery skills, preventing relapse, improving emotional functioning, promoting personal responsibility and reintegrating the individual into work, education, and family life.

(4) Services. Each individual shall receive services each week, including counseling, as provided for in subsection 65D-30.007(6), F.A.C. Each provider shall be capable of providing or arranging for the services listed below. With the exception of counseling, as defined in Rule 65D-30.002, F.A.C., it is not intended that all services listed below be provided. For individuals participating under subsection 65D-30.0037(15) and Rule 65D-30.0048, F.A.C., services shall be provided in accordance with the terms and conditions of the Department of Corrections' contract with the provider. Juvenile Justice Commitment Programs and detention facilities operated by or under contract with the Department of Juvenile Justice are exempt from the requirements of this subsection, but shall provide such services as required in the policies, standards, and contractual terms and conditions established by the Department of Juvenile Justice. Otherwise, services shall be provided in accordance with the needs of the individual as identified in the treatment plan as follows:

- (a) Individual counseling;
- (b) Group counseling;
- (c) Counseling with family members or members of the individual's support system;
- (d) Substance related/recovery-oriented education, such as strategies for avoiding substance use or relapse, health problems related to substance use, and motivational enhancement and strategies for achieving a substance-free lifestyle;
- (e) Life skills training such as anger management, communication skills, employability skills, problem solving, relapse prevention, recovery training, decision-making, relationship skills, and symptom management;
- (f) Expressive therapies, such as recreation therapy, art therapy, music therapy, or dance (movement) therapy to provide the individual with alternative means of self-expression and problem resolution, and other therapies such as evidence-based practices and interventions for substance use or co-occurring conditions;
- (g) Training or education in health and medical issues;
- (h) Employment or educational support services to assist individuals in becoming financially independent; and
- (i) Mental health services for the purpose of:
 - 1. Managing individuals with disorders who are stabilized;
 - 2. Evaluating individuals' needs for in-depth mental health assessment;
 - 3. Training individuals to manage symptoms; and
 - 4. If the provider is not staffed to address primary mental health problems that may arise during treatment, the provider should initiate a timely referral to an appropriate provider for mental health crises or the emergence of a primary mental health disorder, according to the provider's policies and procedures.

(5) Education. As provided for in Section 397.501(6), F.S., in addition to the services required for all programs, education and training must be coordinated or provided to an adolescent, appropriate to his or her needs, in order to maintain his or her educational and intellectual development.

(6) Required Hours of Services.

(a) For level 1, each individual shall receive services each week in accordance with subsection 65D-30.007(4), F.A.C., including at least 14 hours of counseling.

(b) For level 2, each individual shall receive services each week in accordance with subsection 65D-30.007(4), F.A.C., including at least 10 hours of counseling.

(c) For level 3, each individual shall receive services each week in accordance with subsection 65D-30.007(4), F.A.C.,

including at least 4 hours of counseling.

(d) For level 4, each individual shall receive services each week in accordance with subsection 65D-30.007(4), F.A.C., including at least 2 hours of counseling.

In instances in which it is determined that an individual requires fewer hours of counseling in any of the levels of residential treatment, this shall be described and justified in the individual's treatment plan and approved by the qualified professional.

(7) Transportation. Each provider shall arrange for or provide transportation services to individuals who are involved in activities or in need of services, such as mental health, dental, public health, and social services, that are provided at other facilities.

(8) Staff Coverage. For all levels of residential treatment, each provider shall maintain awake, paid staff coverage 24 hours-per-day, 7 days per week.

(9) Caseload. No primary counselor may have a caseload that exceeds 15 currently participating individuals.

Rulemaking Authority 397.321(5) FS. Law Implemented 397.311(26), 397.321, 397.4014, 397.410 FS. History—New 5-25-00, Amended 4-3-03, 8-29-19.

65D-30.008 Standards for Day or Night Treatment with Host Homes.

Rulemaking Authority 397.321(5) FS. Law Implemented 397.311(18)(d), (e), 397.321(1), 397.419 FS. History—New 5-25-00, Amended 4-3-03, Repealed 5-21-12.

65D-30.0081 Standards for Day or Night Treatment with Community Housing.

In addition to Rule 65D-30.004, F.A.C., the following standards apply to day or night treatment with community housing.

(1) Day or Night Treatment with Community Housing is provided on a nonresidential basis at least five (5) hours each day and at least 25 hours each week and is intended for individuals who can benefit from living independently in peer community housing while undergoing treatment. Day or night treatment with community housing is appropriate for individuals who do not require structured, 24-hours-a-day, 7-days-a-week residential treatment. The housing must be provided and managed by the licensed service provider, including room and board and any ancillary services needed, such as supervision, transportation, and meals. Activities for day or night treatment with community housing programs emphasize rehabilitation and treatment services using multidisciplinary teams to provide integration of therapeutic and family services. This component allows individuals to live in a supportive, community housing location while participating in treatment. Treatment shall not take place in the housing where the individuals live, and that the housing is utilized solely for the purpose of assisting individuals in making a transition to independent living.

Individuals who are considered appropriate for this level of care:

(a) Would not have active suicidal or homicidal ideation or present a danger to self or others;

(b) Are able to demonstrate motivation to work toward independence;

(c) Are able to demonstrate a willingness to live in supportive community housing;

(d) Are able to demonstrate commitment to comply with rules established by the provider;

(e) Are not in need of detoxification or residential treatment; and,

(f) Typically need ancillary services such as transportation, assistance with shopping, or assistance with medical referrals and may need to attend and participate in certain social and recovery oriented activities in addition to other required clinical services.

(2) Services. Services shall include counseling as provided for in subsection 65D-30.0081(2), F.A.C. Each provider shall be capable of providing or arranging for the services listed below. With the exception of counseling and life skills training, it is not intended that all services listed be provided. For individuals participating under Rule 65D-30.0048, F.A.C., services shall be provided according to the conditions of the Department of Corrections' contract with the provider. Otherwise, services shall be provided in accordance with the needs of the individual as identified in the assessment and treatment plan, as follows:

(a) Individual counseling;

(b) Group counseling;

(c) Counseling with families or support system;

(d) Substance-related and recovery-focused education, such as strategies for avoiding substance use or relapse, information regarding health problems related to substance use, motivational enhancement, and strategies for achieving a substance-free lifestyle;

(e) Life skills training such as anger management, communication skills, employability skills, problem solving, relapse prevention, recovery management, decision-making, relationship skills, symptom management, and food purchase and preparation;

(f) Expressive therapies, such as recreation therapy, art therapy, music therapy, or dance (movement) therapy to provide the individual with alternative means of self-expression and problem resolution;

(g) Training or provision of information regarding health and medical issues;

(h) Employment or educational support services to assist individuals in becoming financially independent;

(i) Nutrition education;

(j) Mental health services for the purpose of:

1. Managing individuals with disorders who are stabilized,

2. Evaluating individuals' needs for in-depth mental health assessment,

3. Training individuals to manage symptoms; and,

4. If the provider is not staffed to address primary mental health problems that may arise during treatment, the provider shall initiate a timely referral to an appropriate provider for mental health crises or for the emergence of a primary mental health disorder in accordance with the provider's policies and procedures.

(3) Psychiatric and other Medical Services. The need for psychiatric and medical services shall be addressed through consultation or referral when the services cannot be supplied by the provider. Inmate Substance Abuse Programs operated by or under contract with the Department of Corrections or the Department of Management Services are exempt from the requirements of this subsection.

(4) Required Hours of Services. Each individual shall receive a minimum of 25 hours of services per week in accordance with subsection 65D-30.0081(2), F.A.C. This shall include individual counseling, group counseling, or counseling with families or support systems. In instances where a provider requires fewer hours of participation in the latter stages of the individual's treatment process, this shall be clearly described and justified as essential to the provider's objectives relative to service delivery.

(5) Transportation. Each provider shall arrange for or provide transportation services, if needed and as appropriate, to clients who reside in community housing.

(6) Staff Coverage. Each provider shall have an awake, paid employee on the premises at all times at the treatment location when one (1) or more individuals are present. For adults the provider shall have a paid employee on call during the time when individuals are at the community housing location. In addition, the provider shall have an awake, paid employee at the community housing location at all times if individuals under the age of 18 are present.

(7) Caseload. No primary counselor may have a caseload that exceeds 15 individuals.

(8) For individuals in treatment who are granted privilege to self-administer their own medications, provider staff are not required to be present for the self-administration.

Rulemaking Authority 397.321(5) FS. Law Implemented 397.311(26), 397.321, 397.4014, 397.410, 397.487, 397.4873 FS. History--New 12-12-05, Amended 8-29-19, 9-20-20.

65D-30.009 Standards for Day or Night Treatment.

In addition to Rule 65D-30.004, F.A.C., the following standards apply to day or night treatment.

(1) Services. Each individual shall receive services each week. Clinical staff shall provide those services. Each provider shall be capable of providing or arranging for the services listed below. With the exception of counseling, it is not intended that all services listed be provided. For individuals participating under subsection 65D-30.0037(6) and Rule 65D-30.0048, F.A.C., services shall be provided according to the conditions of the Department of Corrections' contract with the provider. Otherwise, services shall be provided in accordance with the needs of the individual as identified in the assessment and treatment plan, as follows:

(a) Individual counseling;

(b) Group counseling;

(c) Counseling with families or support system;

(d) Substance-related and recovery-focused education, such as strategies for avoiding substance use or relapse, information regarding health problems related to substance use, motivational enhancement and strategies for achieving a substance-free lifestyle;

(e) Life skills training in areas such as anger management, communication, employability, problem solving, relapse prevention, decision-making, relationship skills, and symptom management to promote recovery;

(f) Expressive therapies, such as recreation therapy, art therapy, music therapy, or dance (movement) therapy to provide the individual with alternative means of self-expression and problem resolution;

(g) Training or provision of information regarding health and medical issues;

(h) Employment or educational support services to assist individuals in becoming financially independent; and

(i) Mental health services for the purpose of:

1. Managing individuals with disorders who are stabilized;
2. Evaluating individuals' needs for in-depth mental health assessment;
3. Training individuals to manage symptoms; and

4. If the provider is not staffed to address primary mental health problems that may arise during treatment, the provider shall initiate a timely referral to an appropriate provider for mental health crises or the emergence of a primary mental health disorder in accordance with the provider's policies and procedures.

(2) Required Hours of Services. For day or night treatment, each individual shall receive a minimum of at least three (3) hours per day, 12 hours of services per week in accordance with subsection 65D-30.009(1), F.A.C. This shall include individual counseling, group counseling, or counseling with families or support systems, which shall be provided by clinical staff. In instances where a provider requires fewer hours of individual participation in the latter stages of the treatment process, this shall be clearly described and justified as essential to the provider's objectives relative to service delivery.

(3) Psychiatric and other Medical Services. The need for psychiatric and medical services shall be addressed through consultation or referral when the services cannot be supplied by the provider. Inmate Substance Abuse Programs operated by or under contract with the Department of Corrections or the Department of Management Services are exempt from the requirements of this subsection.

(4) Staff Coverage. Each facility shall have an awake, paid employee on the premises at all times when one (1) or more individuals are present.

(5) Caseload. No primary counselor may have a caseload that exceeds 15 individuals.

Rulemaking Authority 397.321(5) FS. Law Implemented 397.311(26), 397.321, 397.4014, 397.410 FS. History—New 5-25-00, Amended 4-3-03, 8-29-19.

65D-30.0091 Standards for Intensive Outpatient Treatment.

In addition to Rule 65D-30.004, F.A.C., the following standards apply to intensive outpatient treatment.

(1) Intensive outpatient services are non-residential, structured treatment providing counseling and education focusing mainly on addiction-related and mental health issues. This community-based treatment allows the individual to apply skills in real world environments. Each provider shall be capable of providing or arranging for the services listed below. With the exception of counseling, it is not intended that all services listed be provided. For individuals participating under subsection 65D-30.0037(6) and Rule 65D-30.0048, F.A.C., services shall be provided according to the conditions of the Department of Corrections' contract with the provider. Otherwise, services shall be provided in accordance with the needs of the individual as identified in the assessment and treatment plan, as follows:

(a) Individual counseling;

(b) Group counseling;

(c) Counseling with families or support system;

(d) Substance-related and recovery-focused education, such as strategies for avoiding substance use or relapse, information regarding health problems related to substance use, motivational enhancement, and strategies for achieving a substance-free lifestyle;

(e) Life skills training such as anger management, communication skills, employability skills, problem solving, relapse prevention, recovery management, decision-making, relationship skills, and symptom management;

(f) Training or provision of information regarding health and medical issues;

(g) Employment or educational support services to assist individuals in becoming financially independent; and

(h) Mental health services for the purpose of:

1. Managing individuals with disorders who are stabilized;
2. Evaluating individuals' needs for in-depth mental health assessment;
3. Training individuals to manage symptoms; and

4. If the provider is not staffed to address primary mental health problems that may arise during treatment, the provider should initiate a timely referral to an appropriate provider for mental health crises or the emergence of a primary mental health disorder in accordance with the provider's policies and procedures.

(2) Required Hours of Services. For intensive outpatient treatment, each individual shall receive at least nine (9) hours of services per week, in accordance with subsection 65D-30.0091(1), F.A.C., including counseling.

(3) Psychiatric and other Medical Services. The need for psychiatric and medical services shall be addressed through consultation or referral when the services cannot be supplied by the provider. Inmate Substance Abuse Programs operated by or under contract with the Department of Corrections and the Department of Management Services are exempt from the requirements of this subsection.

(4) Caseload. No full-time counselor shall have a caseload that exceeds 50 individuals.

(5) Hours of Operation. Providers shall post their hours of operation and this information shall be visible to the public. Inmate Substance Abuse Programs operated by or under contract with the Department of Corrections and the Department of Management Services are exempt from the requirements of this subsection. Juvenile Justice Commitment Programs and detention facilities operated by or under contract with the Department of Juvenile Justice are exempt from the requirements of this subsection but shall provide such services as required in the policies, standards, and contractual conditions established by the Department of Juvenile Justice.

Rulemaking Authority 397.321(5) FS. Law Implemented 397.311(26), 397.321, 397.4014, 397.410 FS. History—New 4-3-03, Amended 8-29-19.

65D-30.010 Standards for Outpatient Treatment.

In addition to Rule 65D-30.004, F.A.C., the following standards apply to outpatient treatment.

(1) Outpatient treatment is provided on a nonresidential basis and is intended for individuals who meet the placement criteria for this component.

(2) Services. Outpatient services provide a therapeutic environment, which is designed to improve the functioning or prevent further deterioration of persons with substance use problems. These services are typically provided on a regularly scheduled basis by appointment, with special arrangements for emergency or crisis situations. Outpatient services may be provided individually or in a group setting. Each individual shall receive services each week. Clinical staff shall provide those services. Each provider shall be capable of providing or arranging for the services listed below. With the exception of counseling, it is not intended that all services listed be provided. For individuals participating under the Department of Corrections, the Department of Juvenile Justice, or the Department of Management Services programs, services shall be provided according to the conditions of the contract with the provider and the respective department. Otherwise, services shall be provided in accordance with the needs of the individual as identified in the assessment and treatment plan, as follows:

(a) Individual counseling;

(b) Group counseling;

(c) Counseling with families or support system;

(d) Substance-related and recovery-focused education, such as strategies for avoiding substance use or relapse, health problems related to substance use, motivational enhancement and strategies for achieving a substance-free lifestyle; and

(e) Crisis intervention.

(3) Required Hours of Services. For outpatient treatment, each individual shall receive services each week in accordance with subsection 65D-30.010(1), F.A.C., including a minimum of one (1) counseling session. If fewer sessions are indicated, justification must be documented in the clinical record.

(4) Caseload. No full-time counselor shall have a caseload that exceeds 50 individuals.

(5) Hours of Operation. Providers shall post their hours of operation and this information shall be visible to the public. Inmate Substance Abuse Programs operated by or under contract with the Department of Corrections, Department of Management Services, Juvenile Justice Commitment Programs, and detention facilities operated by or under contract with the Department of Juvenile Justice are exempt from the requirements of this subsection but shall provide such services as required in the policies, standards, and contractual conditions established by the respective department.

Rulemaking Authority 397.321(5) FS. Law Implemented 397.311(26), 397.321, 397.4014, 397.410 FS. History—New 5-25-00, Amended 4-3-03, 8-29-19.

65D-30.011 Standards for Aftercare.

Aftercare involves structured services provided to individuals who have completed an episode of treatment in a component and who are in need of continued observation and support to maintain recovery. Aftercare services help families and prosocial support

systems reinforce a healthy living environment for individuals with substance use disorders. Relapse prevention education and strategies are important in assisting the individual to recognize triggers and warning signs of regression. Activities include individual participation in daily functions that were adversely affected by substance use impairments before treatment. The provider shall offer services outside normal business hours to accommodate individuals in treatment. In addition to Rule 65D-30.004, F.A.C., the following standards apply to aftercare.

(1) Eligibility. Individuals who have successfully completed intensive inpatient treatment, residential treatment, day or night treatment with community housing, day or night treatment, intensive outpatient treatment, outpatient treatment, or medication-assisted treatment for opioid addiction are eligible for aftercare services.

(2) Services. For individuals participating under the Department of Corrections, the Department of Juvenile Justice, or the Department of Management Services programs, services shall be provided according to the conditions of the contract with the provider and the respective department. Otherwise, services shall be provided in accordance with the needs of the individual as identified in the aftercare plan as follows:

(a) Counseling with a focus on relapse prevention. Providers shall specify the type, frequency, and duration of counseling services to be provided to individuals who are eligible for aftercare. Special care shall be taken to ensure that the provider has flexible hours in order to meet the needs of individuals.

(b) Aftercare Plan. An aftercare plan shall be developed for each individual and the plan shall provide an outline of the goals to be accomplished during aftercare including regular counseling sessions and the need for ancillary services.

(c) Monitoring Progress. Providers shall monitor and document the progress of individuals involved in aftercare and shall review and update the aftercare plan to determine the need for additional services. Individuals shall be monitored with respect to attending appointments, potential for relapse, and results of counseling sessions and other contacts.

Providers shall refer individuals for other needed services as specified in the aftercare plan. This shall include follow-up on all referrals.

(d) Discharge Summary. A written discharge summary shall be completed for individuals who complete services or who leave the provider prior to completion of services. The discharge summary shall include the basis for the individual's discharge, the individual's progress and setbacks during treatment, and recommendations for further services.

Rulemaking Authority 397.321(5) FS. Law Implemented 397.311(26), 397.321, 397.4014, 397.410 FS. History—New 5-25-00, Amended 4-3-03, 12-12-05, 8-29-19.

65D-30.012 Standards for Intervention.

In addition to Rule 65D-30.004, F.A.C., the following standards apply to intervention.

(1) General Intervention. General Intervention includes a single session or multiple sessions of motivational discussion focused on increasing insight and awareness regarding substance use and motivation toward behavioral change. Intervention activities and strategies are used to prevent or impede the development or progression of substance use disorders. Intervention can be tailored for variance in population or setting and can be used as a stand-alone service for those at risk or individuals who meet Intervention Level of care, utilizing a validated tool used for service determination, as a vehicle for engaging those in need of more extensive level of care. Interventions include Treatment Alternatives for Safer Communities (TASC) and Employee Assistance Programs. The following information shall apply to services as described in subsections 65D-30.012(1) and 65D-30.012(2), F.A.C.:

(a) Target Group, Outcomes, and Strategies. Providers shall have current information which:

1. Describes target groups or individuals to be served, including eligibility requirements;
2. Identifies specific clinical outcomes to be achieved; and
3. Describes strategies for these groups or individuals to access needed services.

(b) Services.

1. Supportive Counseling. In instances where supportive counseling is provided, the number of sessions or contacts shall be determined through the intervention plan. In instances where an intervention plan is not completed, all contacts with the individual shall be recorded in the clinical record.

2. Intervention Plan. For individuals involved in intervention services on a continuing basis, the plan shall be completed in accordance with Rule 65D-30.0044, F.A.C. In instances where an intervention plan is not completed, all contacts with the individual shall be recorded in the clinical record. For Treatment Alternatives for Safer Communities programs, the plan shall include requirements the individual is expected to fulfill and consequences should the individual fail to adhere to the prescribed plan,

including provisions for reporting information regarding the individual to the criminal or juvenile justice system or other referral source. Employee Assistance Programs are exempt from the requirement to develop intervention plans.

3. Referral. If during the course of treatment the individual is assessed and determined to need additional services, the provider must have the capability of referring individuals to those services within 48 hours, or immediately in the case of an emergency.

4. Referral. TASC providers shall refer individuals to health care providers or self-help organizations within the court's or criminal justice authority's area of jurisdiction.

(2) Requirements for Treatment Alternatives for Safer Communities (TASC). In addition to the requirements in subsection 65D-30.012(1), F.A.C., the following requirements apply to Treatment Alternatives for Safer Communities.

(a) Eligibility. TASC providers shall establish eligibility standards requiring that individuals considered for intake shall be at-risk for criminal involvement, substance use, or have been arrested or convicted of a crime, or referred by the criminal or juvenile justice system.

(b) Services.

1. Court Liaison. Providers shall establish liaison activities with the court that shall specify procedures for the release of prospective individuals from custody by the criminal or juvenile justice system for referral to a provider. Special care shall be taken to ensure that the provider has flexible operating hours in order to meet the needs of the criminal and juvenile justice systems. This may require operating nights and weekends and in a mobile or an in-home environment.

2. Monitoring. Providers shall monitor and report the progress of each individual according to the consent agreement with the individual. Reports of individual progress shall be provided to the criminal or juvenile justice system or other referral source as required, and in accordance with Sections 397.501(1)-(10), F.S.

3. Intervention Plan. The intervention plan shall include additional information regarding individuals involved in a TASC program. The plan shall be signed and dated by both parties.

4. Referral. Providers shall refer individuals to publicly funded providers within the court's or criminal justice authority's area of jurisdiction, and shall establish written referral agreements with other providers.

5. Discharge/Transfer or Termination Notification. Providers shall report any pending discharge/transfer or termination of an individual to the criminal justice or juvenile justice authority, child welfare authority, or other referral source.

(3) Requirements for Employee Assistance Programs. In addition to the requirements in subsection 65D-30.012(1), F.A.C., the following requirements apply to Employee Assistance Programs.

(a) Consultation and Technical Assistance. Consultation and technical assistance shall be provided by Employee Assistance Programs which includes the following:

1. Policy and procedure formulation and implementation,
2. Training and orientation programs for management, labor union representatives, employees, and families of employees; and,
3. Linkage to community services.

(b) Employee Services. Employee Assistance Programs shall provide services which include linking the individual to a provider, motivating the individual to accept assistance, and assessing the service needs of the individual. The principal services include:

1. Supportive counseling to motivate individuals toward recovery; and,
2. Monitoring.

(c) Resource Directory. Providers shall maintain or have access to a current directory of substance-related, mental health, and ancillary services. This shall include information on Alcoholics Anonymous, Narcotics Anonymous, recovery support programs, public assistance services, and health care services.

(4) Requirements for Case Management. In addition to the requirements in subsection 65D-30.012(1), F.A.C., the following requirements apply to case management in instances where case management is provided as a licensable sub-component of intervention services.

(a) Case Managers. Providers shall identify an individual or individuals responsible for carrying out case management services.

(b) Priority Individuals. Individuals with a need for service priority shall include persons who have multiple problems and needs, and require multiple services or resources to meet those needs.

(c) Case Management Requirements. Case management shall include the following:

1. On-going assessment and monitoring of the individual's condition and progress;
2. Linkage to services as dictated by individual needs;

3. Follow-up on all referrals for other services; and
4. Advocacy on behalf of individuals served.

(d) Contacts. Each case manager shall meet face-to-face with each individual at least monthly unless otherwise justified in the clinical record.

Rulemaking Authority 397.321(5) FS. Law Implemented 397.311(26), 397.321, 397.4014, 397.410 FS. History—New 5-25-00, Amended 4-3-03, 8-29-19.

65D-30.013 Standards for Prevention.

Prevention includes activities and strategies that are used to preclude the development of substance use problems. In addition to Rule 65D-30.004, F.A.C., the following standards apply to prevention.

(1) Categories of Prevention. For the purpose of these rules, prevention services are categorized as indicated, selective, universal direct, or universal indirect, as defined in paragraphs 65E-14.021(4)(v)-(y), F.A.C., incorporated by reference, and available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-10900>.

(2) Specific Prevention Strategies. The following is a description of the specific prevention strategies that are provided through prevention services.

(a) Information Dissemination. This strategy provides knowledge and increases awareness of the nature and extent of alcohol and other drug use, abuse, and addiction, as well as their effects on individuals, families, and communities. It also provides knowledge and increases awareness of available prevention and treatment programs and services. It is characterized by one-way communication from the source to the audience, with limited contact between the two.

(b) Education. This strategy builds skills through structured learning processes. Critical life and social skills include decision making, peer resistance, coping with stress, problem solving, interpersonal communication, and systematic and judgmental abilities. There is more interaction between facilitators and participants than in the information strategy.

(c) Alternatives. This strategy provides participation in activities that exclude alcohol and other drugs. The purpose is to meet the needs filled by alcohol and other drugs with healthy activities, and to discourage the use of alcohol and drugs through these activities.

(d) Problem Identification and Referral Services. This strategy aims to identify those who have engaged in illegal/age-inappropriate use of tobacco or alcohol and individuals who have engaged in the first use of illicit drugs in order to assess if their behavior can be reversed through education. It should be noted however, that this strategy does not include any activity designed to determine if a person is in need of treatment.

(e) Community-Based Process. This strategy provides ongoing networking activities and technical assistance to community groups or agencies. It encompasses neighborhood-based, grassroots empowerment models using action planning and collaborative systems planning.

(f) Environmental. This strategy establishes or changes written and unwritten community standards, codes, and attitudes, thereby influencing alcohol and other drug use by the general population.

(3) General Requirements.

(a) Staffing Patterns. Providers shall delineate reporting relationships and staff supervision. This shall include a description of staff qualifications, including educational background and experience regarding the substance use prevention field. Providers shall have at least one (1) qualified professional on staff.

(b) Referral. Providers shall have a plan for assessing the appropriateness of prevention services and conditions for referral to other services. The plan shall include a current directory of locally available substance use services and other human services for referral of prevention program participants, or prospective participants.

(c) Referral. Providers shall have a plan for assessing the appropriateness of prevention services and conditions for referral to other services. The plan shall include a current directory of locally available substance abuse services and other human services for referral of prevention program participants, or prospective participants.

(4) Requirements for Providers of Universal Direct and Universal Indirect Prevention Services.

(a) Program Description. Providers of universal direct and universal indirect prevention services shall describe the prevention services that will be available. This description shall include:

1. The target population, including relevant demographic factors (if known),
2. The risk and protective factors to be addressed (if known),

3. The specific prevention strategies identified in subsection 65D-30.013(2), F.A.C., to be utilized,
4. The appropriateness of these services to address risk and protective factors (if these are known); and,
5. How the effectiveness of the services will be evaluated.

(b) Activity Logs for Providers of Universal Direct and Universal Indirect Prevention Services. Providers shall collect and maintain records of all universal direct and universal indirect prevention services, including the following:

1. A description of the characteristics of the target population;
2. The risk and protective factors to be addressed (if known);
3. A description of the activities, including the specific prevention strategies used;
4. The duration of the activities;
5. The number of participants;
6. The location of service delivery; and,
7. The date of the activity.

(5) Requirements for Providers of Selective Prevention Services.

(a) Program Description. Providers of selective prevention services shall describe the prevention services that will be available.

This description shall include:

1. The target population, including relevant demographic factors;
2. The risk and protective factors to be addressed;
3. The specific prevention strategies identified in subsection 65D-30.013(2), F.A.C., to be utilized;
4. The appropriateness of these services to address identified risk and protective factors; and
5. How the effectiveness of the services will be evaluated.

(b) Activity Logs for Providers of Selective Prevention Services. Providers shall collect and maintain records of all universal direct and universal indirect prevention services, including the following:

1. A description of the characteristics of the target population;
2. The risk and protective factors to be addressed;
3. A description of the activities, including the specific prevention strategies used;
4. The duration of the activities;
5. The number of participants;
6. The location of service delivery; and
7. The date of the activity.

(6) Requirements for Providers of Indicated Prevention Services.

(a) Program Description. Providers of indicated prevention services shall describe the prevention services that will be available.

(b) This description of indicated prevention services shall include:

1. The target population, including relevant demographic factors;
2. The risk and protective factors to be addressed;
3. The specific prevention strategies identified in subsection 65D-30.013(2), F.A.C., to be utilized;
4. The appropriateness of these services to address identified risk and protective factors; and
5. How the effectiveness of the services will be evaluated.

Rulemaking Authority 397.321(5) FS. Law Implemented 397.311(26), 397.321, 397.410 FS. History--New 5-25-00, Amended 4-3-03, 8-29-19.

65D-30.014 Standards for Medication-Assisted Treatment for Opioid Use Disorders.

(1) State Authority. The state authority is the Department's Office of Substance Abuse and Mental Health. The State Opioid Treatment Authority (SOTA) is the individual designated by the Office of Substance Abuse and Mental Health to exercise the state's authority and responsibilities in governing opiate treatment by opioid treatment programs. The SOTA acts as the state's coordinator for the development and regulatory monitoring of opioid treatment programs and serves as a liaison with the appropriate federal, state and local agencies.

(2) Federal Authority. The federal authority is the Center for Substance Abuse Treatment.

This rule shall remain in effect for a period of five years after its effective date and shall be reviewed by the Department for its continued necessity at least 90 days before its expiration.

Rulemaking Authority 397.321(5) FS. Law Implemented 397.311(26), 397.321, 397.410, 397.427 FS. History--New 5-25-00, Amended 4-3-03, 6-

25-19, 8-10-20.

65D-30.0141 Needs Assessment for Medication-Assisted Treatment for Opioid Use Disorders.

(1) Determination of Need.

(a) The Department shall annually perform the assessment detailed in the “Methodology of Determination of Need Methadone Medication-Assisted Treatment,” CF-MH 4038, May 2019, incorporated by reference and available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-11993>. The Department shall publish the results of the assessment in the Florida Administrative Register by June 30. Facilities owned and operated by the Florida Department of Corrections are exempt from the needs assessment process. However, these facilities must apply for a license to deliver this service.

(b) The publication shall direct interested parties to submit a letter of intent to apply for licensure to provide medication-assisted treatment for opioid use disorders to the Regional Office of Substance Abuse and Mental Health where need has been demonstrated.

1. The publication shall provide a closing date for submission of letters of intent.
2. Interested parties must identify the fiscal year of the needs assessment to which they are responding and the number of awards they are applying for per county identified in the assessment in their letter of intent.

(c) Within seven (7) business days of the closing date, the Regional Office shall notify parties who submitted a letter of intent on how to proceed.

1. If the number of letters of intent equals or is less than the determined need, parties shall be awarded the opportunity to proceed to licensure by completing an “Application for Licensure to Provide Substance Abuse Services” form, C&F-SA Form 4024, May 2019, incorporated by reference and available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-11996>.

2. If the number of letters of intent exceeds the determined need, parties shall be invited to submit a “Methadone Medication-Assisted Treatment (MAT) Application to Proceed to Licensure Application” form, CF-MH 4041, May 2019, incorporated by reference and available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-11995>. Applications may not be rolled over for consideration in response to a needs assessment published in a different year and may only be submitted for a current fiscal year needs assessment.

a. The Department shall utilize an evaluation team made up of industry experts to conduct a formal rating of applications as stipulated in the “Methadone Medication-Assisted Treatment (MAT) Application Evaluation” form, CF-MH 4040, May 2019, incorporated by reference and available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-11994>. The evaluation team members shall not be affiliated with the Department, current methadone medication-assisted treatment providers operating in Florida, or the applicants.

b. The selection of a provider shall be based on the following criteria:

(I) Capability to Serve Selected Area(s) of Need and Priority Populations. Area(s) of Need are the counties identified as having a need for additional clinics. Priority Populations are pregnant women, women with young children, and individuals with financial hardships;

(II) Patient Safety and Quality Assurance/Improvement;

(III) Scope of Methadone Medication-Assisted Treatment Services;

(IV) Capability and Experience; and

(V) Revenue Sources.

c. Applicants with the highest-scored applications in each county shall be awarded the opportunity to apply for licensure for the number of programs specified in their letter of intent to meet the need of that county. If there is unmet need, the next highest scored applicant(s) will receive an award(s) based on the remaining need and the number of programs specified in their letter of intent. This process will continue until the stated need is met. Regional offices shall inform the highest-scoring applicant(s) in writing of the award.

d. All awarded applicants must submit a letter of intent to apply for licensure to the appropriate regional office within 30 calendar days after the award. If an applicant declines an award or fails to submit the letter of intent within the specified time, the Department shall rescind the award. After the Department rescinds the original award for that selected area of need, the applicant with the next highest score shall receive the award.

(2) Awarded applicants must receive at least a probationary license within two (2) years of receipt of an award letter connected to their “Methadone Medication-Assisted Treatment (MAT) Application to Proceed to Licensure Application” form, CF-MH 4041. If an applicant fails to obtain a probationary license within the specified time, the Department shall rescind the award. See Rule

65D-30.0036, F.A.C. for licensure application requirements. Applicants may submit a request to the State Authority and Substance Abuse and Mental Health Program Office for an exception if unable to meet timeframes due to a natural disaster that causes physical damage to the applicant's building(s). Proof of natural disaster and impact on physical property must accompany the request. Upon receipt of the request for exception and accompanying proof, a one-time extension shall be granted for six (6) months. Providers who are delayed for a reason other than a natural disaster may petition the Department for a rule waiver pursuant to Section 120.542, F.S.

This rule shall remain in effect for a period of five years after its effective date and shall be reviewed by the Department for its continued necessity at least 90 days before its expiration.

Rulemaking Authority 397.321(5) FS. Law Implemented 397.311(26), 397.321, 397.407, 397.410, 397.427 FS. History—New 8-10-20.

65D-30.0142 Clinical and Operational Standards for Medication-Assisted Treatment for Opioid Use Disorders.

(1) General Requirements.

(a) Methadone Medication-Assisted Treatment Program Sponsor. The methadone medication-assisted treatment sponsor, as defined in subsection 65D-30.002(42), F.A.C., of a new provider shall be a licensed health professional and shall have worked in the field of substance use 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 treating substance use disorders.

(c) Special Permit and Consultant Pharmacist.

1. Special Permit.

a. All providers 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 Department.

b. Providers obtaining a special pharmacy permit shall hire a consultant pharmacist licensed by the state of Florida.

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

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

b. Provide ongoing pharmaceutical consultation;

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

d. Meet face-to-face, at least quarterly, with the medical director to review the provider's pharmacy practices. Meetings shall be documented in writing and signed and dated by both the consultant pharmacist and the medical director;

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 visit the provider 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, 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 SOTA.

(d) Providers shall develop policies and procedures for the treatment of pregnant women.

1. Prior to the initial dose, each female shall be fully informed of the risks of taking and not taking methadone during pregnancy, including possible adverse effects on the mother or fetus. If the medication is not taken, risk includes withdrawal syndrome which has been associated with fetal demise. The individual 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.

2. Pregnant individuals shall be informed of the opportunity and need for prenatal care by referral to publicly or privately funded health care providers. The provider shall establish a documented system for referring individuals to prenatal care.

3. In the event there are no publicly funded prenatal referral resources to serve those who are indigent, or if the 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 record.

4. When the individual is referred for prenatal services, the practitioner to whom she is referred shall be notified that she is undergoing methadone 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 refuses referral and prenatal instruction and counseling, the provider shall obtain a signed statement from the individual acknowledging that she had the opportunity for the prenatal care but declined.

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

6. 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.

(e) Minimum Responsibilities of the Physician. Physicians must adhere to best practice standards for an individual receiving methadone medication-assisted treatment. Best practices are evidence-based practices which are subject to scientific evaluation for effectiveness and efficacy. Best practice standards may be established by entities such as the Substance Abuse and Mental Health Services Administration, national trade associations, accrediting organizations recognized by the Department, or comparable authorities in substance use treatment. In addition, the 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 record before the individual receives the initial dose of 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;

3. To ensure that justification is recorded in the clinical record for any change to the frequency of visits to the provider for observed medication ingesting, including cases involving the need for exemptions, or when prescribing medication for physical or emotional problems;

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

5. The initial assessment for methadone medication-assisted treatment shall be conducted in person. Each subsequent assessment shall be conducted, either in-person or via telehealth, with each individual at least annually, including evaluation of the individual's physical/medical status, 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.P.R.N. under the supervision of a physician. The protocol shall include criteria and the conditions under which the assessment would be conducted more frequently.

(f) Central Registry.

1. Providers shall register and participate in the Department-approved electronic 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, §2.13. The provider must submit to information gathering activities by the SOTA for state planning purposes.

2. Methadone shall not be administered or dispensed to an individual who is known to be currently enrolled with another provider. Providers shall develop policies and procedures to ensure compliance with 42 C.F.R. 8.12(g)2. If an individual changes providers, the current provider shall assist with coordinating the transfer to another provider. The evidence of linkage to care shall be noted in the clinical 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 the Central Registry.

3. Individuals applying for methadone medication-assisted 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.

4. If an individual is found trying to secure or has succeeded in obtaining duplicate doses of methadone or other medication, the individual 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 or their qualified designee shall evaluate the individual as soon as medically feasible for continuation of treatment. In addition, a record of violations by individuals must become part of the clinical record maintained by all participating providers and shall be made available to Department staff upon request.

5. With the application for licensure, providers shall submit with the application for licensure written plans for participating in registry activities.

(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 least 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 attempted contact, individual's name, date of birth, address, and contact information.

3. Priority must be given to pregnant woman and HIV-positive individuals.

(h) Operating Hours and Holidays.

1. Providers shall post operating hours in full view of the public. This information shall include hours for counseling and administering medication.

2. All providers shall be open Monday through Saturday. Providers shall have medicating hours and counseling hours that accommodate individuals, 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. This includes individuals on Phase 1, individuals on a 30 to 180-day detoxification regimen, and individuals who need daily observation. Providers shall develop 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 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 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 during holidays, if clinically advisable. Services shall be accessible to individuals for whom take-home medication is not clinically advisable. Individuals who fall into this category shall receive a minimum of seven (7) days notification regarding arrangements and exact hours of operation.

(2) Maintenance Treatment Standards.

(a) Standards for Placement.

1. Determining Addiction and Placement.

a. An individual aged 18 or over shall be placed in treatment 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 is currently physiologically addicted to opioid drugs and became physiologically addicted at least one (1) year before placement in methadone medication-assisted treatment.

b. A one (1)-year history of addiction means that individuals seeking placement in methadone medication-assisted treatment were physiologically addicted to opioid drugs at least one (1) year before placement and were addicted continuously or episodically for most of the year immediately prior to placement with 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 to treatment if, by the evidence presented and observed, and utilizing reasonable clinical judgment, the physician or their qualified designee concludes that the individual was physiologically addicted during the year prior to placement. Such observations shall be recorded in the clinical record by the physician or their qualified designee.

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. Individuals who are diagnosed with a primary opioid use disorder and a chronic pain condition are eligible for admission.

2. Placement of Individuals Under 18 Years of Age.

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

b. The physician or their qualified designee shall document in the clinical record that the individual continues to be or is again physiologically dependent on opioid drugs and is appropriate for placement.

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, 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. In addition to the minimum requirements for completing a treatment plan, providers shall conduct the following:

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. During treatment plan review, the counselor shall re-assess present level of functioning, course of treatment, and identify future goals.

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) Exemption from Minimum Standards for Placement.

1. An individual who has resided in a penal or chronic-care institution for one (1) month or longer may be placed in 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 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. 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 record.

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

(d) Pregnant individuals.

1. Pregnant individuals, 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. For such individuals, 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 may be placed on a medication-assisted treatment regimen using a medication other than methadone only upon the written order of a physician who determines this to be the best choice of therapy for that individual.

3. Evidence of current or prior addiction and criteria used to determine such findings shall be recorded in the clinical 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. Up to 2 years after discharge or detoxification for opioid use disorders, and individual who has been previously involved in methadone medication-assisted 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 treatment to be medically justified.

2. Evidence of prior treatment and the criteria used to determine such findings shall be recorded in the clinical record by the physician or their qualified designee. The physician or their qualified designee shall sign and date the information recorded in the

clinical record.

(f) Denying an Individual Treatment.

1. If an individual will not benefit from a treatment regimen that includes the use of methadone or other opioid treatment medications, or if treating the individual would pose a danger to others, the individual may be refused treatment. This is permitted even if the individual meets the standards for placement.

2. The physician or their qualified designee shall make this determination and shall document the basis for the decision to refuse treatment.

(g) Methadone Take-home Privileges.

1. Take-home doses of methadone are permitted only for individuals participating in a methadone medication-assisted treatment program. Requests for take-home doses greater than the amount allowed, as stipulated in paragraph (2)(h) of this rule, must be entered into the Substance Abuse and Mental Health Services Administration/Center for Substance Abuse Treatment (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 12-month period of time per request;
- b. Justification;
- c. Indicate compliance with securing methadone in a lockable secure container;
- d. Statement of supporting documentation on file; and
- e. Any other information the provider deems necessary in support of the request.

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

3. When considering an individual's 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.

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

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 to obtain their medication.

(h) Take-home Phases. To be considered for take-home privileges, all individuals shall be in compliance with criteria as stated in 42 CFR 8.12(i)(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. Take-home privileges shall be limited to the following:

- a. During the first 90 days of treatment, the take-home supply is limited to a single dose each week. The individual shall ingest all other doses under appropriate medical supervision.
- b. In the second 90 days of treatment, the take-home supply is limited to two doses per week.
- c. In the third 90 days of treatment, the take-home supply is limited to three doses per week.
- d. In the remaining months of the first year, an individual may be given a maximum of six-day supply of take-home medication.
- e. After one year of continuous treatment, an individual may be given a maximum two-week supply of take-home medication.
- f. After two years of continuous treatment, an individual may be given a maximum of one-month supply of take-home medication, but must make monthly visits.

3. Diversion Control Requirements.

a. All individuals in medical maintenance shall receive their medication orally in the form of liquid, diskette or tablet. Diskettes and tablets are allowed if formulated to reduce potential parenteral abuse.

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

c. All criteria for take-home privileges as listed under paragraph (2)(g) shall continue to be met.

(i) Transferred Individuals and Take-Home Privileges.

1. Any individual 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. The physician at the previous provider shall also document that the individual met all criteria for their current phase and are at least on Phase I.

2. Any individual who transfers from out-of-state is required to comply with the criteria stated in 42 CFR 8.12(i)(2), and with verification of previous clinical records, the physician shall determine the phase level based on the individual's history.

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

1. Results of the latest physical examination,
2. Results of the latest laboratory tests on blood and urine,
3. Results of drug screens for the past 12 months,
4. Medical history,
5. Current dosage level and dosage regimen for the past 12 months,
6. Documentation of the conditions which precipitated the referral;
7. A written summary of the individual'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 medications 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 arrival at the provider to which he or she is transferred. Providers shall not withhold an individual's records when requested by the individual for any reason, including failure to pay bills owed to the provider. The referring provider shall forward the records directly to the provider of the individual's choosing with signed records releases from the individual.

(k) Exemptions from Take-Home Privileges and Phasing Requirements.

1. Exemptions for Disability or Illness.

a. If an individual is found to have a physical disability which interferes with the individual's ability to conform to the applicable mandatory schedule, the individual 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 is also found to be responsible in handling opioid treatment medication, is making progress in treatment, and is providing drug screens free of illicit substances.

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

2. Temporary Reduced Schedule of Attendance

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

b. Any individual using prescription opioid medications or sedative medication not used in the medication-assisted treatment protocols shall provide a legitimate prescription from the prescribing medical professional. 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 or qualified designee. Such determination of necessity shall be recorded in the clinical record by the physician or their qualified designee who shall sign and date these entries. An individual 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. The state and federal authorities shall review exemption requests and render a decision in accordance with the criteria identified in 42 CFR 8.12(i)(1) and (2).

3. Travel Distance.

a. In those instances where access to a provider is limited because of travel distance, the physician is authorized to reduce the frequency of an individual's attendance. This is permitted if the individual is currently employed or attending a regionally approved educational or vocational program or the individual 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 record by the physician who shall

sign and date these entries. The state and federal authorities shall review the requests for reducing the frequency of attendance and render a decision in accordance with the criteria identified in 42 CFR 8.12(i)(1) and (2).

4. Other Travel.

a. Any exemption that is granted to an individual regarding travel shall be documented in the clinical record. Such documentation shall include tickets prior to a trip, copies of boarding passes, copies of fuel receipts, lodging receipts, or other verification of the individual's arrival at the approved destination. If travel is due to medical treatment, documentation shall include a physician's note or related documentation from the physician or qualified designee. 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. The state and federal authorities shall review these requests for take-homes in excess of 27 doses and render a decision in accordance with the criteria identified in 42 CFR 8.12(i)(1) and (2).

b. Individuals who receive exemptions for travel shall be required to submit to a drug screening on the day of return to the provider.

(l) Random Drug Screening.

1. Individuals in the first six (6) months of treatment shall be required to submit to at least one (1) monthly random drug screen.

2. Individuals who are on Phase III or higher shall be required to submit to a minimum of eight (8) random drug screens per year of an individual's treatment plan.

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 opioids, methadone, buprenorphine, amphetamines, benzodiazepines, and cocaine. If there is a history of prescription opioid analgesic abuse, an expanded toxicology panel that includes these opioids shall administered. Additional testing is based on individual patient need and local drug use patterns and trends.

4. The physician or their qualified designee shall review all positive drug screens from illicit substances in accordance with the medical protocol established in subsection 65D-30.004(7), F.A.C.

(m) Employment of Persons on a Maintenance Protocol. No staff member, 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 federal and state 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) Caseload. No full-time counselor shall have a caseload that exceeds the equivalent of 50 currently participating individuals. Participating individual equivalents are determined in the following manner.

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

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

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

(o) Termination from Treatment.

1. There will be occasions when individuals will need to be terminated from treatment. Individuals 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 illicit substances; or

e. Do not effectively participate in treatment programs to which they are referred.

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

2. Providers shall establish criteria for involuntary termination from treatment. All individuals shall be given a copy of these criteria upon placement and shall sign and date a statement that they have received the criteria.

(p) Withdrawal from Maintenance.

1. The physician or qualified designee shall ensure that all individuals in methadone medication-assisted 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 progress in treatment and the justification for continued maintenance. The assessment and recommendations shall be recorded in the clinical record.

2. All providers shall develop policies and procedures that establish a process to assist individuals served in attaining recovery goals, thereby enabling transition to a lower level of care. At least annually, during the treatment plan review, the provider shall assess the individual's readiness and desire to transition to a lower level of care and shall provide information about the titration of medication to maintain therapeutic levels or to withdraw from the medication with the least necessary discomfort. Transition is gradual, individualized, and actively involves the individual served and the next provider to ensure effective coordination and engagement.

3. An individual being withdrawn from treatment shall be closely supervised during withdrawal. A dosage reduction schedule shall be established by the physician or qualified designee 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 or qualified designee and the individual.

(q) Services.

1. Comprehensive Services. A comprehensive range of services shall be available to each individual as required in Section 397.427(1), F.S. The type of services to be provided shall be determined by individual needs, the characteristics of individuals served, and the available community resources.

2. Counseling.

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

b. A counseling session shall be at least 30 minutes in duration, conducted in a private room, and shall be documented in the clinical 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 of residence;

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 the kit for use during all program hours of operation.

(3) Medication Units.

(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 compliance with the Department and applicable regulating agencies. The licensed provider and medication unit must be owned by the same provider.

(b) A medication unit's services shall comply with the requirements 42 CFR 8.2 and 42 CFR 8.11(i).

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

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 addresses unmet need;

3. Copy of state license and federal certifications;

4. Required qualifications and job description for Medical Director, clinical on-site Director or Manager, and proposed staffing for the medication unit;

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

services;

6. Plans to secure proper zoning before medication unit opening; and
7. Plans on how medication unit will ensure individuals receive comprehensive support services such as counseling.
8. An affirmative statement that the primary full-service program agrees to retain responsibility for care;
9. An affirmative statement that the medication unit is limited to administering and dispensing the narcotic treatment medications and collecting samples for drug screening or analysis.

(d) Medication units must open within two (2) years of receiving approval. Providers who are delayed for a reason other than a natural disaster may petition the Department for a rule waiver pursuant to Section 120.542, F.S.

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

(5) Other Medications.

(a) Buprenorphine Products. Qualified medical personnel licensed to practice in the state of Florida and meeting all federal requirements can prescribe buprenorphine to individuals under their license. Medical personnel shall comply with federal regulations related to buprenorphine products.

(b) Naltrexone Products. Naltrexone can be prescribed by any healthcare provider who is licensed to prescribe medications. Healthcare providers must meet all federal requirements and shall conform to federal regulations related to naltrexone products.

(c) Providers shall adhere to the prevailing federal and state requirements regarding the use of opioid treatment medications in the maintenance treatment of individuals who are or become pregnant during the course of treatment.

This rule shall remain in effect for a period of five years after its effective date and shall be reviewed by the Department for its continued necessity at least 90 days before its expiration.

(6) This rule will be reviewed and repealed, modified, or renewed through the rulemaking process five years from the effective date.

Rulemaking Authority 397.321(5) FS. Law Implemented 397.311(26), 397.321, 397.410, 397.427 FS. History—New 8-10-20, Amended 5-19-22.