

DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF SUBSTANCE ABUSE AND MENTAL HEALTH

Statutory Authority: 16 Delaware Code, §§2205(10), 2207(a) and 2208(b)
(16 Del.C. §§2205(10), 2207(a) & 2208(b))

PROPOSED

PUBLIC NOTICE

6001 Substance Abuse Facility Licensing Standards

In accordance and compliance with the procedures set forth at 29 Del.C. §1131, *et seq.* and 29 Del.C. §10101, *et seq.*, the Delaware Department Health and Social Services (DHSS) / Division of Substance Abuse and Mental Health (DSAMH) is proposing to repeal the current Substance Use Treatment Program Licensure Standards, located at 16 DE Admin. Code 6001, and replace them in their entirety with the following proposed regulation. Copies of the proposed regulations are available in the June *Register of Regulations* or by contacting DSAMH as provided below.

Any person who wishes to make written suggestions, compilations of data, testimony, briefs or other written materials concerning the proposed new standards must submit same to Bryan Gordon, Provider Relations Unit, Division of Substance Abuse and Mental Health, 1901 North DuPont Highway, New Castle, Delaware 19720 or by fax to 302-255-4427 no later than 4:30 p.m. on June 30, 2015.

The action concerning the determination of whether to adopt the proposed regulation will be based upon the results of Department and Division staff analysis and the consideration of the comments and written materials filed by other interested persons.

SUMMARY OF PROPOSAL

The purpose of this notice is to advise the public that DHSS/DSAMH is proposing to adopt revised Substance Use Treatment Standards under its authority as defined in Delaware Code, Title 16, Chapter 22.

I. Statutory Authority.

16 Del.C. §2205(10); 16 Del.C. §2207(a); 16 Del.C. §2208(b)

II. Brief Synopsis of the Subject, Substances, and Issues.

The current Substance Use Treatment Standards were adopted in 2010. Since that time there have been some pertinent changes in the treatment of drug and alcohol use disorders; and there has been an adoption of the American Society of Addiction Medicine (ASAM) Level of Care Criteria by DSAMH. The proposed regulations make changes to all parts of the Substance Use Treatment Licensure Standards, including definitions, licensure criteria, suspension and revocation of licenses, and integration of ASAM criteria into program standards.

III. Possible Terms of Agency Action.

There is not a sunset date for this regulation.

IV. Other Regulations that May Be Affected by the Proposal.

None known.

V. Notice of Public Comment.

Under the provisions of Title 29, Chapter 101 of the Delaware Code, DHSS/DSAMH gives notice and provides an open comment period for thirty (30) days to allow all stakeholders an opportunity for public input regarding any proposed change in its standards for establishing Substance Use Treatment Licensure Standards. Comments must be submitted to:

Bryan Gordon

Provider Relations Unit, Division of Substance Abuse and Mental Health

1901 North DuPont Highway

New Castle, Delaware 19720

or by fax to 302-255-4427

All comments must be received no later than 4:30 p.m. on June 30, 2015.

Upon final adoption of these Standards by DHSS/DSAMH, they will be posted on the DSAMH web site and all current licensed programs will be notified via email of their adoption.

6001 Substance Abuse Facility Licensing Standards

1.0 Purpose

The Department is issuing these regulations to promote the health and well being of consumers/clients receiving services in substance abuse treatment facilities located within the State of Delaware. They are not intended to limit additional contract standards for substance abuse treatment facilities and programs with which a service provider may be expected to comply.

2.0 Authority and Applicability

The Department is authorized by 16 ~~Del.C.~~, Ch. 22 to license and regulate substance use disorder and co-occurring treatment facilities. These regulations shall apply to any facility as defined in 16 ~~Del.C.~~, Ch. 22, and Ch. 51 and address the minimum acceptable standards and programmatic conditions for consumers/clients receiving services in substance use disorder and co-occurring disorder treatment facilities. No organization or entity shall manage or operate a substance abuse treatment facility within the State of Delaware unless it has been so licensed by the Department.

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3.0 Definitions

The following words and terms, when used in these regulations, shall have the following meaning unless the context clearly indicates otherwise:

“Adjunct and alternative therapy” means a specific modality of therapy based on a specific valid body of knowledge, provision of which requires specific credentials. Examples include, but are not limited to, Psychodrama; Art Therapy; Music Therapy; Acupuncture; Massage Therapy; EMDR; etc.

“Administrator” means an individual who is authorized by the governing body to provide overall management of the agency.

“Admission” means the point in a client’s relationship with a program when the intake process has been completed and the program begins to provide additional services.

“Advisory Council” means a group of individuals approved by the governing body, to provide community input and recommendations to the governing body.

“Agency” means any partnership, corporation, association, or legal entity except for an individual practitioner, that provides, is seeking to provide, or holds itself out as providing alcohol and/or other drug treatment or rehabilitation services. An agency may operate more than one program.

“Applicant” means any agency that has submitted a written application for a license to operate an alcohol and/or other drug abuse treatment or rehabilitation program in Delaware.

“Client” means an individual who receives, or has received services from an agency.

“Client Record” means the official legal written file for each client containing all the information required by these regulations, and maintained to demonstrate compliance with these regulations.

“Clinical director” means an individual who, by virtue of education, training, and experience, satisfies the requirements of §6.1.2.1 and/or §16.2.3 of these regulations and is authorized by the Administrator to provide clinical oversight of the treatment program. The Clinical director may also serve as Clinical supervisor when directed to do so by the agency’s governing body.

“Clinical supervisor” means an individual who, by virtue of education, training, and experience, satisfies the requirements of §6.1.3.1 of these regulations; and is authorized by the Administrator and/ or the governing body to provide clinical supervision for all clinical staff.

“Continuing care” means those services recommended to the client upon discharge from a program that support and increase the gains made during the client’s treatment at that program.

“Counseling” means the process in which a Counselor I or Counselor II works with a client, family, significant other, or a group of clients, families or significant others, to assist them to understand issues, consider alternatives, and change behaviors.

- Individual counseling is the face-to-face, video or telephone interaction between a Counselor I or Counselor II and an individual client for a specific therapeutic purpose.
- Family counseling is the face-to-face interaction between a Counselor I or Counselor II and the family member(s)/significant other(s) of a client for a specific therapeutic purpose.
- Group counseling is the face-to-face interaction between a Counselor I or Counselor II and two or more clients or clients’ families/significant others for a specific therapeutic purpose.

~~“Counselor I” means an individual who, by virtue of education, training, and experience meets the requirements of §6.1.4.1 of these regulations and functions under the supervision of a Clinical supervisor.~~

~~“Counselor II” means an individual who, by virtue of education, training, and experience, meets the requirements of §6.1.5.1 of these standards and functions under the supervision of a Clinical supervisor.~~

~~“Cultural Competence” means acceptance and respect for difference, continuing self-assessment regarding culture, careful attention to the dynamics of difference, continuous expansion of cultural knowledge and resources, and a variety of adaptations to service models in order to better meet the needs of minority populations. Culturally competent agencies work to hire unbiased employees, seek advice and consultation from the minority community, and actively decide what they are and are not capable of providing to minority clients. (March, 1989, Towards a Culturally Competent System of Care, Volume 1, National Technical Assistance Center for Children’s Mental Health, Georgetown University Child Development Center, p. 17.)~~

~~“Day” unless otherwise specified, one (1) day is a calendar day.~~

~~“Deemed status” means a licensure standing approved by DSAMH and bestowed upon programs that have been accredited by an accreditation body approved by DSAMH. Programs that have been granted Deemed Status will be inspected in accordance with §4.3.2 of these standards.~~

~~“Designee” means the person who is delegated tasks, duties, and responsibilities when such designation is permitted by these regulations.~~

~~“Discharge” means the point at which a client’s active involvement with an agency is terminated.~~

~~“Division/DSAMH” means the Delaware Division of Substance Abuse and Mental Health within the Delaware Department of Health and Social Services.~~

~~“Division Director” means the Director of the Delaware Division of Substance Abuse and Mental Health within the Delaware Department of Health and Social Services, or his/her designee.~~

~~“Documentation” means a written record acceptable as evidence to substantiate compliance with these regulations.~~

~~“DSM” means the Diagnostic and Statistical Manual of Mental Disorders, most recent edition, as published by the American Psychiatric Association.~~

~~“Facility” means the physical area, grounds, building(s) or portions thereof, under direct program administrative control.~~

~~“Follow up” means the process for determining the status of an individual who has been referred to an outside resource for services or who has been discharged from services OR the process for determining an agency’s compliance with these standards after an agency audit has been completed.~~

~~“Governing Body” means the individual or individuals responsible for the overall management of an agency, responsible for ensuring compliance with 5.0 of these regulations.~~

~~“Initial Recovery Plan” means the first recovery plan developed on the first day of treatment. The initial recovery plan is a working document created with input from the client and program staff.~~

~~“Intake” means the gathering of personally identifying and clinical data required to determine whether a client should be admitted to a program.~~

~~“Intern” means a student who performs counseling functions under the supervision of a **Clinical supervisor**.~~

~~“License” means the document issued by the Division that authorizes a program to provide alcohol and/or other drug treatment or rehabilitation.~~

~~“Licensed Nurse” means a Registered Nurse or a Licensed Practical Nurse.~~

~~“Licensed Practical Nurse” means a person licensed by the State of Delaware as a Practical Nurse or a person licensed by a state that participates in the National Licensure Compact (NLC).~~

~~“Licensure” means the process by which the Division determines whether or not a program is in compliance with these regulations.~~

~~“Medical history” means history of and any treatment of allergies, head injuries, nervous disease/disorders, seizure disorder, or delirium tremens, surgery, major accidents, fractures, venereal diseases, cardiovascular, respiratory, endocrine, gastrointestinal diseases or disorders, and gynecological-obstetrical history, including current involvement in prenatal care and current medical treatment by a Primary Care Physician or other medical doctor.~~

~~“Needs Assessment” means a systematic evaluation of current system and programmatic operations and projected needs. This evaluation is performed as part of the Quality Assurance Plan and focuses on the changing needs of the community and population served.~~

~~“Nurse Practitioner” means a person licensed by the State of Delaware as a Nurse Practitioner or a person licensed by a state that participates in the National Licensure Compact (NLC).~~

~~"Periodic Recovery Plan Review/Revision" is a process whereby the clinical supervisor, and counselor, review prior recovery plans and establish new goals based on the client's progress and/or changing needs through out treatment.~~

~~"Physician" means a person licensed to practice medicine in the State of Delaware.~~

~~"Physician Assistant" means a person licensed by the State of Delaware as a Physician Assistant.~~

~~"Policy" means a statement of the principles that guide and govern the activities, procedures and operations of a program.~~

~~"Procedure" means a series of activities designed to implement the policies of a program.~~

~~"Program" means the location or facility where an agency provides or offers to provide any of the various modalities of service when such services are provided or offered on a regularly scheduled basis. Clinical participation records of clients are EITHER stored on-site OR readily available to staff in electronic format using computer hardware that is installed or regularly available on-site.~~

~~"Protocols" means a written rule developed by an agency to govern specific procedures or certain activities.~~

~~"Provisional License" means the document issue by the Division that authorizes a program to provide alcohol and/or other drug treatment or rehabilitation for up to one hundred and eighty (180) days when the applicant is not in compliance with these regulations or is applying for licensure for the first time.~~

~~"Public place" means an area accessible to clients, employees or visitors; the main entry or hallway; the reception area or foyer; or the dining or multipurpose room.~~

~~"Qualified Medical Personnel" means a physician, physician's assistant, or nurse practitioner, licensed by the State of Delaware.~~

~~"Qualified Psychiatric Practitioner" means a physician or nurse practitioner, licensed by the State of Delaware with specific clinical experience in the treatment of substance use disorders as well as mental health disorders. Qualified Psychiatric Practitioners must have specific training in the use of buprenorphine and Opioid antagonist medications as well as the use of psychotropic medications used with individuals who have a mental health diagnosis.~~

~~"Quality Assurance" means the process of objectively and systematically monitoring and evaluating the quality and appropriateness of client care to identify and resolve identified issues.~~

~~"Readmission" means the point in a client's relationship with an agency when a client has been discharged, subsequently reapplied for admission, intake has been completed, and the agency begins to provide services again.~~

~~"Registered Nurse" means a person licensed by the State of Delaware as a registered nurse or a person licensed by a state that participates in the National Licensure Compact (NLC).~~

~~"Shall" means a mandatory procedure, the only acceptable method under these regulations.~~

~~"Signature/Signed" means, at a minimum, the writers' first initial, last name, title or credentials and date or an authentic digital signature OR the client or legal guardian's first and last name and/or date when required.~~

~~"Significant other" means an individual, whether or not related by blood or marriage, on which another individual relies for support.~~

~~"Staff" means full-time and part-time employees, consultants and volunteers, students/interns.~~

~~"Treatment" means the process a client undergoes to understand his or her alcohol or drug use and/or mental health diagnosis and choices made to change his or her behavior.~~

~~"Volunteer" means a person who, without direct financial compensation, provides services to a program.~~

~~"Waiver" means the exemption from compliance with a requirement of these regulations.~~

~~14 DE Reg. 471 (11/01/10)~~

~~4.0 License Application Procedures~~

~~4.1 Applicability~~

~~4.1.1 Any entity seeking to operate a substance use treatment program or a co-occurring, (substance use disorder with mental health disorders) treatment program shall be licensed in accordance with these regulations for each program it seeks to operate. Each facility's license shall list one or more categories of service that the facility is authorized to provide and the facility's location.~~

~~4.1.1.1 Program categories for which licenses may be issued are:~~

~~4.1.1.1.1 Residential Detoxification: substance use disorders~~

~~4.1.1.1.2 Ambulatory Detoxification (Amdetox):~~

~~4.1.1.1.3 Outpatient Treatment: substance use disorders or co-occurring disorders,~~

~~4.1.1.1.4 Opioid treatment: substance use disorders,~~

- 4.1.1.1.5 Residential Treatment: substance use disorders,
- 4.1.1.1.6 Transitional residential treatment: substance use disorders.

4.2 Application Procedures

- 4.2.1 The Division may supply an application packet to all applicants upon request. Applications can also be obtained by visiting the Division's website at: www.dhss.delaware.gov/dhss/dsamh/regs.html.
- 4.2.2 All persons and agencies applying for the first time for a license shall schedule a meeting with DSAMH Quality Assurance staff for the purpose of receiving needed technical assistance regarding the licensure criteria and procedures.
- 4.2.3 A separate application shall be completed for each program at each location at which an agency intends to operate a substance use disorder and/or co-occurring program.
- 4.2.4 The applicant may withdraw the application at any time by notifying the Division in writing.

4.3 Required Information

- 4.3.1 An applicant for licensure shall submit the following information on forms provided by the Division:
 - 4.3.1.1 Name and address of the applicant;
 - 4.3.1.2 Name, address and qualifications of the agency director, program director and/or partners, including copies of the professional licenses each has been issued by the State of Delaware;
 - 4.3.1.3 Articles of incorporation and bylaws, and/or partnership agreement;
 - 4.3.1.4 Name and address, occupation and place of employment, of the program director, board members, advisory board members, and officers.
 - 4.3.1.5 A chart of the staff organization with names and qualifications;
 - 4.3.1.6 A description of the services to be provided by the program, including a statement of the program philosophy, goals, and objectives and a description of the methodology for each service element;
 - 4.3.1.7 A copy of the program's complete proposed policies and procedures manual if the application is for initial licensure;
 - 4.3.1.8 Documentation of applicable insurance coverage, including protection of the physical and financial resources of the program; coverage for all people, buildings and equipment; professional and general liability insurance; workers' compensation; fidelity bonding sufficient to cover all client funds, property and interests; and automobile insurance when vehicles owned by the program are used for client transportation;
 - 4.3.1.9 A floor plan for any facility not previously licensed;
 - 4.3.1.10 For residential and detoxification facilities, the maximum client capacity requested; and
 - 4.3.1.11 A copy of the program's business license, if required.
- 4.3.2 Applicants applying for Deemed Status shall meet all standards as outlined in §17.0, §18.0 and §19.0 of these standards (as applicable).
- 4.3.3 Applicants shall supply all information requested on the application. The completed application shall be accompanied by a \$15.00 fee in accordance with 16 Del.C. §2205. The Division shall not consider any application until it is properly completed and payment has been received.

4.4 Application Processing

- 4.4.1 The Division shall determine whether an application is complete and shall notify the applicant in writing if additional information is required to complete the application or determine the applicant's compliance with these regulations.
- 4.4.2 The Division shall investigate and consider each completed application. An applicant for renewal shall submit its completed application at least ninety (90), but not more than one hundred and twenty (120), days before its current license expires.

4.5 Investigations and Inspections

- 4.5.1 By applying for or accepting a license, an applicant or licensee authorizes the Division and its representatives to conduct the inspections and investigations necessary to determine compliance with applicable licensing standards.
- 4.5.2 Agencies applying for licensure shall have the following information available for inspection by the Division:
 - 4.5.2.1 Materials demonstrating compliance with all related Federal, State and local statutes, ordinances, rules and regulations [e.g., fire, health, building, American's with Disabilities Act] applicable to the facility being licensed;
 - 4.5.2.2 A copy of the program's policies and procedures manual as required in §5.1.4;
 - 4.5.2.3 Materials demonstrating compliance with the relevant sections of Provisions Regarding Modalities of these regulations; and

- 4.5.2.4 ~~Materials demonstrating compliance with all other applicable licensing authorities and accreditation authorities when applicable.~~
- 4.5.3 ~~Investigations and inspections may include on-site inspections of the program and its operation; inspection and copying (in accordance with 42 CFR Part 2 and HIPAA 45 CFR Parts 160 and 164) of program records, clinical records and other documents maintained by the program; and acquisition of other information, including otherwise privileged or confidential information from any other persons who may have information bearing on the applicant's or licensee's compliance or ability to comply with these regulations.~~
- 4.5.4 ~~The Division shall review, update and when necessary, amend these regulations no less than every three (3) years.~~
- 4.6 ~~Division Report~~
 - 4.6.1 ~~Upon completion of any inspection, the Division shall compile a Survey Summary Report citing strengths and recommendations for addressing deficiencies in meeting these standards.~~
 - 4.6.2 ~~The Division shall schedule an exit interview with each program for review of the Survey Summary Report.~~
- 4.7 ~~Corrective action plans~~
 - 4.7.1 ~~Within ten (10) working days after the receipt of a survey summary report, the program shall submit a corrective action plan to the Division, addressing all areas where recommendations were made, unless otherwise directed by the Division.~~
 - 4.7.2 ~~The corrective action plan shall include a description of the corrective measures the program will take to address the regulation cited in the survey summary report, a target date for implementation of each corrective measure, and a description of the preventive measures implemented to ensure ongoing compliance with these regulations.~~
 - 4.7.3 ~~The Division may perform follow up on-site inspections to review the implementation of corrective action plan(s).~~
- 4.8 ~~Actions on applications for licensure~~
 - 4.8.1 ~~On the basis of the information supplied by the applicant and any other information acquired during its investigation and inspection, the Division may take any one of the following actions:~~
 - 4.8.1.1 ~~Issue or renew a full license for a period of up to two years when the Division determines a program is in *substantial compliance* with Chapter 22 of Title 16 **Del.C.**, and these regulations, and/or has been granted Deemed Status or~~
 - 4.8.1.2 ~~Issue or renew a full license for a period of up to one year when the Division determines a program is in *compliance* with Chapter 22 of Title 16 **Del.C.**, and these regulations;~~
 - 4.8.1.3 ~~Issue or renew a full license for a period of up to one year when the Division determines a program that has been granted Deemed Status is not in compliance with Chapter 22 of Title 16 **Del.C.** and these regulations or regulations set forth by the accreditation body; or~~
 - 4.8.1.4 ~~Issue a provisional license for up to one hundred and eighty (180) days when the program is not in compliance with Chapter 22 of Title 16 **Del.C.**, or regulations set forth by the accreditation body upon which Deemed Status has been granted (when applicable) and the applicant's failure to meet the requirements of Chapter 22 of Title 16 **Delaware Code** and these regulations does not jeopardize the health, safety and well-being of clients. The Division may issue one renewal of a provisional license for a period not to exceed ninety (90) days. (The Division's decision to issue a provisional license instead of a full license is final and not subject to administrative appeal;) or~~
 - 4.8.1.5 ~~Issue a temporary license for up to ninety (90) days when additional time is required by the Division to inspect or investigate the program, additional time is required by the applicant to undertake remedial measures or complete a corrective action plan, when the program's failure to meet the requirements of Chapters 22 and 51 of Title 16 Delaware Code, and these regulations does not jeopardize the health, safety and well-being of clients. A temporary license is not renewable and shall expire automatically without notice or hearing. (The Division's decision to issue a temporary license instead of a full or provisional license is final and not subject to administrative appeal;) or~~
 - 4.8.1.6 ~~Revoke, suspend or deny a license in accordance with §4.9 and §4.10.~~
 - 4.8.2 ~~The Division may issue a single renewal of a license, for one (1) year, without an on-site inspection by the Division.~~
 - 4.8.3 ~~The Division shall notify the program by mail, phone, email or any combination of the above of its licensure decision.~~
- 4.9 ~~Access by the Division~~

- 4.9.1 A program is subject to review, which may include on site inspection, with or without notice, by the Division.
- 4.9.2 The Division's right to monitor shall include complete access to all clients, staff, board members, and to all client, staff, financial and administrative program records needed for the purposes of monitoring or evaluation of the program's compliance with these regulations, financial auditing or for research. The Division may review and copy records in accordance with 42 CFR Part 2 and HIPAA 45 CFR parts 160 and 164.
- 4.10 Nonassignability; Change in circumstances; Posting
 - 4.10.1 A license for the operation of a substance use program applies to both the program and the premises upon which the program operates. Licenses are not transferable, remain the property of the Division, and shall be returned upon request.
 - 4.10.2 A program's current license shall be posted in a public place at its facility.
 - 4.10.3 The Division issues each license on the basis of information available to it on the date the license is issued. An program or licensee shall give written notice to the Division of any change of program name, ownership, governing authority, premises or location a minimum of thirty (30) days before such change takes effect. The Division will determine within fifteen (15) days whether a new application is required.
 - 4.10.4 Any person or entity acquiring a licensed substance use program shall apply for a new license in accordance with these regulations.
 - 4.10.5 A licensee shall notify the Division in writing sixty (60) days prior to a voluntary closure of any program it is operating. The notice shall detail how the licensee will comply with §8.1.4.
 - 4.10.6 The licensee shall provide written notice to clients no less than thirty (30) days prior to closure and shall make reasonable efforts to place clients in appropriate programs in compliance with §8.1.3.
- 4.11 Relationship to funding
 - 4.11.1 The issuance of a license to a program is not a commitment of by the Division to fund the program.
- 4.12 Reasons for denial, suspension or revocation of license
 - 4.12.1 A license may be denied, suspended or revoked for one or more of the following reasons:
 - 4.12.1.1 When a program submits false information to the Division for licensing purposes;
 - 4.12.1.2 When a program fails to cooperate with the Division in connection with a licensing inspection or investigation;
 - 4.12.1.3 When a program has deviated from the category of service listed on its license;
 - 4.12.1.4 When an applicant or program fails to be in compliance with the requirements of these regulations for the types of services for which application was made or for which the program was licensed, as outlined in §4.1.
 - 4.12.1.5 When an applicant or program fails to implement the corrective action plan it submitted pursuant to §4.7, unless the Division approves an extension or modification of the corrective action plan;
 - 4.12.1.6 When a program has violated any part of Title 16 ~~Del.C.~~, Chapter 22 or these regulations;
 - 4.12.1.7 When a program has a history of, or currently demonstrates, financial insolvency, such as
 - 4.12.1.7.1 Filing for bankruptcy;
 - 4.12.1.7.2 Being subjected to foreclosure, eviction for failure to pay rent, or termination of utility services for failure to pay bills; or
 - 4.12.1.7.3 Failing to pay such taxes as employment or social security in a timely manner.
 - 4.12.1.8 When the program is in violation of a safety or sanitation law or regulation and fails to correct the violation;
 - 4.12.1.9 When the program, its governing body or owner participates in, condones or is associated with fraud, deceit, coercion, misrepresentation or any other illegal act;
 - 4.12.1.10 When the program, or any of its personnel or governing body violate professional ethics;
 - 4.12.1.11 When the program, or any of its personnel or governing body, permits, aids or abets the commission of an unlawful act within its facilities or permits, aids or abets the commission of an unlawful act involving chemical substances within the program; or
 - 4.12.1.12 When the program, or any of its personnel or governing body, has participated in, condoned, associated with or knows or should have known and has permitted the continuation of any other practice that jeopardizes the safety or health or well being of any client.
- 4.13 Procedure when a license is denied, suspended or revoked
 - 4.13.1 In accordance with 16 ~~Del.C.~~ 2208, when the Division determines that an applicant or licensee fails to meet minimum compliance with the requirements of these regulations for the types of services for which

application was made or for which the program was licensed or has committed an act or engaged in conduct or practices justifying denial, suspension or revocation of licensure:

- 4.13.1.1 The Division shall notify the applicant or licensee by certified mail, return receipt requested, of its intent to deny, suspend or revoke the license. The "Notice of Intended Action" shall include the particular reason(s) for the proposed action and provision for a fair hearing.
 - 4.13.2 Within ten (10) days after receipt of the "Notice of Intended Action," an applicant or licensee may request a hearing by delivering a written request to the Division Director in person or by certified mail, return receipt requested. If no such request is made within ten (10) days, the Secretary of the Department shall proceed to deny, revoke or suspend said license as set forth in the notice of proposed action.
 - 4.13.3 Within fifteen (15) days after receipt of an applicant's or licensee's request for a hearing, the Division Director shall issue a "Notice of Hearing" to the applicant or licensee and to the public. The "Notice of Hearing" shall include a statement of the time, place and nature of the hearing, a statement of the legal authority and jurisdiction under which the hearing is to be held; a reference to the particular provisions of the statutes and rules involved; and a short and plain statement of the matters asserted.
 - 4.13.4 All hearings conducted under this subsection shall be governed by procedures authorized by rules of the Department; the Department or its agent may take testimony concerning any matter within its jurisdiction and may administer oaths, summons or subpoenas for any witness and subpoenas duces tecum, which shall be served and returned as provided by law.
 - 4.13.5 At the hearing, the applicant or licensee shall have the right to cross-examine witnesses against it, produce witnesses in its favor and to appear personally or by counsel.
 - 4.13.6 All hearings shall be open to the public and a full record and transcript of the proceedings shall be prepared. The Secretary of the Department shall make a determination, which shall specify the Department's findings of fact and conclusions. A copy of the determination shall be sent by certified mail, return receipt requested, or be personally served upon the applicant or licensee.
 - 4.13.7 Copies of the transcription may be obtained by any interested party on payment of the cost of preparing such copies.
- 4.14 Procedure for reinstatement of suspended or revoked license
- 4.14.1 If the licensee has not previously had a license revoked or suspended under these rules, it may, at any time after the suspension or revocation determination is final, request a hearing for the purpose of showing that the reasons for revocation or suspension of the license have been corrected and that the license should be reinstated.
 - 4.14.2 No licensee who has previously had a license suspended or revoked under these rules may request a hearing to reinstate the license prior to one year after the determination becomes final.
 - 4.14.3 The request for a hearing shall be in writing and shall be delivered to the Secretary of the Department in person or by certified mail, return receipt requested.
 - 4.14.4 Any hearing conducted under this subsection shall not operate to stay or supersede any decision revoking or suspending a license.
 - 4.14.5 Hearings under this subsection shall be conducted in accordance with 29 ~~Del.C.~~ Chps. 100 and 101 and 4.13 of these regulations.
- 4.15 Waiver
- 4.15.1 An application for a waiver from a requirement of these regulations shall be made in writing to the Division's Director of Quality Assurance; it shall specify the regulation from which waiver is sought, demonstrate that each requested waiver is justified by substantial hardship, and describe the alternative practice(s) proposed. The waiver request shall be posted in a prominent place in the facility and outline a process approved by the Division whereby clients can offer comments and feedback specific to the waiver request. The Division's Director of Quality Assurance Unit shall make a recommendation of action on the application to the Division Director or designee. The Division Director or designee will review the request and recommendations and make final waiver request decisions.
 - 4.15.2 No waiver shall be granted if such action would result in an activity or condition that would endanger the health, safety or well-being of a client.
 - 4.15.3 A waiver granted under these regulations shall be in effect for the term of the applicant's license. If a waiver is required for an additional period of time, it shall be requested as part of the licensure renewal process in accordance with §4.15.
 - 4.15.4 An adverse decision by the Division on a request for a waiver may be appealed in accordance with §4.13.
 - 4.15.5 The granting of a waiver does not constitute a modification of any requirement of these regulations.

4.15.6 Licensees shall notify the Division within ten (10) working days when a waiver granted by the Division is no longer needed.

4.15.7 The Division Director may revoke a waiver when the alternative practice proposed in the application for waiver is determined to be ineffectual.

4.15.8 The Division Director may revoke the waiver when the program fails to implement the alternative practice as proposed in the application for waiver.

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Part II—General Provisions

5.0 Standards Applicable to all Facilities and Programs

5.1 Governance

5.1.1 Governing Body/Advisory Council.

5.1.1.1 Every community-based agency shall have a governing body and/or advisory council that includes representatives of the population it serves.

5.1.1.2 The governing body shall be legally responsible for overseeing all management and operations of the agency and for ensuring compliance with applicable laws and regulations by approving all of the agency's staffing, documentation and overall operations:

5.1.1.2.1 Written by laws;

5.1.1.2.2 Mission;

5.1.1.2.3 Goals;

5.1.1.2.4 Policies and Procedures; and

5.1.1.2.5 Budget.

5.1.1.3 The authority and duties of the governing body shall include:

5.1.1.3.1 Ensuring that the agency director, program directors, clinical supervisors and Counselors employed by the agency meet the requirements of §6.1 of these regulations.

5.1.1.3.2 Establishing and reviewing:

5.1.1.3.2.1 Policies and procedures governing the overall management of the program including:

5.1.1.3.2.1.1 Policies and procedures manual; (§5.1.4),

5.1.1.3.2.1.2 Fiscal management policies and procedures; (§5.1.5),

5.1.1.3.2.1.3 Personnel policies and procedures; (§5.1.6.2), and

5.1.1.3.2.1.4 Compliance with these regulations.

5.1.1.4 The Governing Body will meet, at a minimum, one (1) time per year. Documentation of its annual review shall be entered into the minutes of its meeting.

5.1.2 Meetings and minutes of meetings.

5.1.2.1 Minutes of all meetings shall include:

5.1.2.1.1 Names of members who attended;

5.1.2.1.2 Names of members absent;

5.1.2.1.3 Date of meeting;

5.1.2.1.4 Topics discussed and decisions reached.

5.1.2.2 The minutes shall be available for review by the Division.

5.1.3 Administrative Staff

5.1.3.1 Administrator

5.1.3.1.1 The governing body shall appoint an agency director.

5.1.3.1.2 The qualifications, authority, and duties of the agency director shall be defined in writing.

5.1.3.1.3 The Governing body shall ensure that, at the time of employment, the agency director is familiar with the job description and job responsibilities of the position, these regulations, and the agency's policies and procedures as maintained in compliance with §5.1.4.

5.1.4 Policies and procedures manual:

5.1.4.1 Each program shall have a manual of written policies from which written procedures have been derived to address operations and services. The program's policies and procedures manual shall be:

5.1.4.1.1 A complete document;

- 5.1.4.1.2 Readily available to staff.
- 5.1.4.2 ~~The program's policies and procedures manual shall be reviewed at least annually by the governing body or its designee.~~
- 5.1.4.3 ~~The review shall be documented in the meeting minutes.~~
- 5.1.4.4 ~~The manual shall include:~~
 - 5.1.4.4.1A ~~statement of program philosophy and goals, including:~~
 - 5.1.4.4.1.1 ~~Geographical area to be served;~~
 - 5.1.4.4.1.2 ~~Population to be served;~~
 - 5.1.4.4.1.3 ~~Types of services offered;~~
 - 5.1.4.4.1.4 ~~Organization chart,~~
 - 5.1.4.4.1.5 ~~Policies and procedures to ensure compliance with §5.1.5, Fiscal management;~~
 - 5.1.4.4.1.6 ~~Personnel files~~
 - 5.1.4.4.1.7 ~~The intake procedures~~
 - 5.1.4.4.1.8 ~~The diagnostic assessment procedure established program director in compliance with §8.1.2.1.7.~~
 - 5.1.4.4.1.9 ~~Referral criteria policies and procedures.~~
 - 5.1.4.4.1.10 ~~Admission criteria policies and procedures;~~
 - 5.1.4.4.1.11 ~~Discharge criteria policies and procedures that specify conditions under which clients may be involuntarily discharged, including client behavior that constitutes grounds for discharge by the program.~~
 - 5.1.4.4.1.12 ~~Established procedures consistent with 42 CFR §2.12(c)(5) and HIPAA 45 CFR parts 160 and 164 that staff shall follow when discharging a client involved in the commission of a crime on the premises of the program or against its staff, including designation of the person who shall make a report to the appropriate law enforcement program;~~
 - 5.1.4.4.1.13 ~~Established procedures consistent with 42 CFR Part 2 and HIPAA 45 CFR parts 160 and 164 that staff shall follow when a client leaves against medical or staff advice and the client may be dangerous to self or others;~~
 - 5.1.4.4.1.14 ~~Confidentiality policy and procedures that comply with 42 CFR Part 2 and HIPAA 45 CFR parts 160 and 164;~~
 - 5.1.4.4.1.15 ~~Policies and procedures in regard to completion and utilization of all forms used by the program;~~
 - 5.1.4.4.1.16 ~~Policies and procedures for making mandated reports of suspected child abuse or neglect in compliance with 16 Del.C. §§902 through 904, 3910, 1132, 2224, 5194 and 42 CFR § 2.12(c)(6) (including non-retaliation policies when personnel report abuse and neglect.);~~
 - 5.1.4.4.1.17 ~~Policies and procedures for communicating with law enforcement personnel when a client commits or threatens to commit a crime on program premises or against program personnel, in compliance with 42 CFR § 2.12(c)(5) and HIPAA 45 CFR parts 160 and 164;~~
 - 5.1.4.4.1.18 ~~Policies and procedures for mandated reporting of infectious or contagious diseases, in compliance with state law and 42 CFR Part 2 and HIPAA 45 CFR Parts 160 and 164;~~
 - 5.1.4.4.1.19 ~~Medication policies and procedures, in compliance with the Delaware State Boards of Medical Practice, Nursing, and Pharmacy;~~
 - 5.1.4.4.1.20 ~~Policies and procedures, as applicable, for the collection of urine specimens;~~
 - 5.1.4.4.1.21 ~~Policies and procedures for responding to medical emergencies;~~
 - 5.1.4.4.1.22 ~~Policies and procedures regarding clients' rights~~
 - 5.1.4.4.1.23 ~~Code of ethics; and~~
 - 5.1.4.4.1.24 ~~Policies and procedures for reporting any violations of law or codes of ethics to the appropriate certification and/or licensure boards.~~
- 5.1.5 ~~Fiscal management policies and procedures and record keeping~~
 - 5.1.5.1 ~~Each program shall establish written policies and procedures regarding fiscal management that shall be maintained in compliance with generally accepted accounting principles.~~
- 5.1.6 ~~Personnel policies and procedures.~~
 - 5.1.6.1 ~~Each program shall develop and maintain a written personnel manual that shall include:~~
 - 5.1.6.1.1 ~~Staff rules of conduct consistent with due process including:~~
 - 5.1.6.1.1.1 ~~Examples of conduct that constitute grounds for disciplinary action;~~

- 5.1.6.1.1.1.2 Examples of unacceptable performance that constitute grounds for disciplinary action;
- 5.1.6.1.1.1.3 Policies and procedures on mental health, and alcohol and drug abuse problems of staff (including staff member assistance policies and procedures);
- 5.1.6.1.2 Safety and health of staff, including:
 - 5.1.6.1.3 Rules about any required medical examinations and rules about communicable diseases that could affect the health or safety of the program's clients or staff.
- 5.1.6.2 Each agency shall maintain a separate personnel file for each staff member in a manner that ensures the privacy of agency staff.
- 5.1.6.3 The personnel file shall include at a minimum:
 - 5.1.6.3.1 the name and telephone number of a person the agency can contact in an emergency;
 - 5.1.6.3.2 The current job title and job description signed by the staff member;
 - 5.1.6.3.3 Either:
 - 5.1.6.3.3.1 an application for employment signed by the staff member; or
 - 5.1.6.3.3.2 a resume;
 - 5.1.6.3.4 A copy of the staff member's license and/or current alcohol or other drug Counselor certification and/or Co-Occurring Counselor's certification.
 - 5.1.6.3.5 The results of reference investigations and verification of experience, training and education, including:
 - 5.1.6.3.5.1 primary source verification of the staff member's educational degree certificate(s), based on job description;
 - 5.1.6.3.5.2 primary source verification of the staff member's license(s), and/or certification(s), as applicable, based on job description;
 - 5.1.6.3.5.3 A statement signed by the staff member acknowledging that s/he understands the requirements of 42 USC §290dd-2, 42 CFR Part 2 and HIPAA 45 CFR parts 160 and 164;
 - 5.1.6.3.5.4 Documentation of the staff member's annual written performance evaluation;
 - 5.1.6.3.5.4.1 Any disciplinary actions taken against the staff member;
 - 5.1.6.3.5.4.2 Formal corrective action taken, that:
 - 5.1.6.3.5.4.2.1 The staff member has signed;
 - 5.1.6.3.5.4.2.2 His/her immediate supervisor has signed;
 - 5.1.6.3.5.5 A copy of the staff member's training plan, as required in §5.1.7.1;
 - 5.1.6.3.5.6 Documentation of the staff member's abilities to provide culturally competent services; and
 - 5.1.6.3.5.7 Documentation of in-service training and continuing education as required by §5.1.7.
- 5.1.6.4 Counselor II's personnel files shall also include:
 - 5.1.6.4.1 Documentation that the Counselor II is working toward meeting the requirements of §6.1.5; and
 - 5.1.6.4.2 Documentation of Supervision as required in §12.2.4.
- 5.1.6.5 Records documenting all required staff member health clearances, including any medical test results required by agency policy shall be made available to the Division upon request.
- 5.1.7 Staff training and development
 - 5.1.7.1 Each program shall establish a written staff training and development plan. The plan shall include:
 - 5.1.7.1.1 An orientation curriculum, that will ensure that all staff are familiar with the agency policies and procedures, and have a working knowledge of at least the following:
 - 5.1.7.1.1.1 Personnel policies and procedures, regarding the health and safety of staff, established in compliance with §5.1.6.1.2;
 - 5.1.7.1.1.2 Program policies and procedures regarding the reporting of cases of suspected child abuse or neglect in compliance with 16 Del.C. §§902 through 904, 910, 1132, 2224, 5194 and 42 CFR § 2.12(c)(6), including non-retaliation policies when personnel report abuse and neglect;
 - 5.1.7.1.1.3 Program policies and procedures regarding client's rights established in compliance with §7.1, as applicable;
 - 5.1.7.1.1.4 Instruction and training in the elements of the fire plan in compliance with §9.2;
 - 5.1.7.1.1.5 Program policies and procedures regarding the obligation to report violations of law and applicable codes of ethics to the appropriate certification and/or licensure boards, established in compliance with §5.1.4.4.1.24.

6.0 Standards Applicable to all Facilities and Programs

6.1 Staff Qualifications for Substance use Disorders Treatment Staff

6.1.1 Qualifications for the Position of Administrator

6.1.1.1 Each agency shall have an administrator responsible for the overall management of the agency and/or program and staff.

6.1.1.2 Each administrator hired or promoted on or after the date these regulations become effective shall have at a minimum:

6.1.1.2.1A Bachelor's Degree from an accredited college or university with at least 5 years of documented experience in human services including:

6.1.1.2.1.1at least two (2) years of experience in substance abuse treatment; and

6.1.1.2.1.2at least two (2) years of management experience.

6.1.2 Qualifications for the Position of Clinical Director

6.1.2.1 Each individual, hired or promoted, to the position of Clinical Director on or after the date these regulations become effective shall have, at a minimum:

6.1.2.1.1A master's degree in counseling or a related discipline and five (5) years of documented clinical experience in human services, at least three (3) years of which shall be in substance use services.

6.1.2.1.2A Bachelor's Degree from an accredited college or university with a major in chemical dependency, psychology, social work, counseling, nursing or a related field, full certification as a certified alcohol and drug Counselor (CADC) or certified co-occurring disorder professional (CCDP) in the state of Delaware or by a nationally recognized organization in addictions counseling and five (5) years of documented experience in substance use services.

6.1.3 Qualifications for the Position of Clinical Supervisor

6.1.3.1 Each individual authorized, hired, or promoted, to provide clinical supervision on or after the date these regulations become effective shall meet one of the following:

6.1.3.1.1A Bachelor's Degree from an accredited college or university with a major in chemical dependency, psychology, social work, counseling, nursing or a related field of study and full certification as a certified alcohol and drug Counselor (CADC) or certified co-occurring disorder professional (CCDP) in the state of Delaware or by a nationally recognized organization in addictions counseling; or

6.1.3.1.2A Bachelor's Degree from a accredited college or university with a major in chemical dependency, psychology, social work, counseling, nursing or a related field of study and five (5) years of documented clinical experience in the substance abuse treatment field.

6.1.4 Qualifications for the Position of Counselor I

6.1.4.1 Each individual hired or promoted on or after the date these regulations become effective shall meet one of the following requirements:

6.1.4.1.1Full certification as a certified alcohol and drug Counselor (CADC) in the state of Delaware; or

6.1.4.1.2Full certification by a nationally recognized body in addictions counseling or co-occurring counseling; or

6.1.4.1.3Five (5) years of clinical experience working in the field of substance abuse treatment.

6.1.5 Counselor II

6.1.5.1 Qualifications for the Position of Counselor II

6.1.5.1.1A person who does not meet the educational and experiential qualifications for the position of Counselor as set forth in §6.1.4 may be employed as an Counselor II if the requirements of at least one of the following paragraphs are met:

6.1.5.1.1.1The individual has worked in the substance abuse treatment field for less than five years.

6.1.5.1.1.2The individual is a student enrolled in a course of study while completing a practicum or internship;

6.1.5.1.1.3The individual is working toward full certification in addictions counseling or co-occurring counseling by the Delaware Certification Board or a nationally recognized certification organization.

6.1.5.2 Counselor IIs must receive clinical supervision by the clinical supervisor a minimum of one (1) hour per every twenty (20) hours of clinical services provided to clients.

6.1.5.3 The clinical supervisor must review all documentation developed by the Counselor II for accuracy and clinical appropriateness.

6.1.5.3.1 The review shall be documented and placed in the Counselor II's personnel file.

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7.0 Standards Applicable to all Facilities and Programs

7.1 Clients' Rights

7.1.1 Nondiscrimination policy

7.1.1.1 No program shall deny any person equal access to its facilities or services on the basis of race, color, religion, ancestry, sexual orientation, gender expression, national origin, or disability.

7.1.1.2 No program shall deny any person equal access to its facilities or services on the basis of age or gender, except those programs that specialize in the treatment of a particular age group (such as adolescents) or gender (such as mothers and infants).

7.1.1.3 All agencies shall ensure that they comply with the federal Americans with Disabilities Act, 28 U.S.C. §§12101 et seq. and 28 Code of Federal Regulations, Part 36 (July 1991) and 16 **Del.C.** §2220.

7.1.2 Enumerated Rights

7.1.2.1 All agencies shall ensure that clients' rights are fully protected as enumerated in Del.C. §2220 and, including the following:

7.1.2.1.1 To be free from retaliation for exercising any enumerated right.;

7.1.2.1.2 To file a grievance or complaint with the program in accordance with its policy and procedures. Procedures for receiving, investigating, hearing, considering, responding to and documenting grievances shall:

7.1.2.1.2.1 Include a procedure for receipt of grievances from clients or persons acting on their behalf;

7.1.2.1.2.2 Provide for the investigation of the facts supporting or disproving the grievance;

7.1.2.1.2.3 Identify the staff responsible for receipt and investigation of grievances;

7.1.2.1.2.4 Be posted in a public place;

7.1.2.1.3 Participate, and/or have others of his/her choice participate, in an informed way in the grievance process.

7.1.2.1.4 To be informed that participation in treatment is voluntary, except as provided in 16 **Del.C.** §§2211, 2212, 2213 and 2215;

7.1.2.1.5 To refuse service, except as provided in 16 **Del.C.** §§2211, 2212, 2213 and 2215. If consequences, such as termination from other services, may result from such refusal, that fact shall be:

7.1.2.1.5.1 Documented in the client's file.

7.1.2.1.6 To be free of any exploitation or abuse by any program personnel or any member of the governing body.

7.1.2.1.7 To be assured that any incident of abuse, neglect or mistreatment will be reported in accordance with §5.1.4.4.1.16.

7.1.2.1.8 To communicate with legal counsel.

7.1.2.1.9 To confidentiality of all records, correspondence and information relating to assessment, diagnosis and treatment in accordance with 42 U.S.C. § 290dd-2, 42 CFR Part 2 and HIPAA 45 CFR parts 160 and 164.

7.1.2.1.10 To review his/her own records in accordance with 42 U.S.C. § 290dd-2, 42 CFR Part 2 and HIPAA 45 CFR parts 160 and 164.

7.1.2.1.11 Client request for review and a summary of the review if granted shall be documented in the client's record.

7.1.2.2 Participation in experimental or research programs

7.1.2.2.1 No client shall participate in any experimental or research project without the full knowledge, understanding and written consent of that client (and/or legal guardian, when appropriate).

7.1.2.2.2 All experimental or research projects shall be conducted in full compliance with applicable state and federal laws, regulations and guidelines.

7.1.3 Barriers to treatment:

7.1.3.1 The program shall make reasonable modifications in policies, practices and procedures and/or provide assistive services to accommodate clients who are unable to participate in treatment due

to language, cultural, literacy barriers or disabilities, unless doing so would fundamentally alter the nature of the services offered.

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8.0 Standards Applicable to all Facilities and Programs

8.1 Clinical records

8.1.1 Maintenance of client records

8.1.1.1 Programs shall:

8.1.1.1.1 Maintain a record for each client that is

8.1.1.1.1.1 Accurate;

8.1.1.1.1.2 Legible and

8.1.1.1.1.3 Signed by the staff member who provided the service.

8.1.1.1.2 Maintain a standardized client record-keeping system, with client records that are uniform in format and content;

8.1.1.1.3 Establish and maintain a system that permits easy identification of and access to individual client records by authorized program staff;

8.1.1.1.4 Comply fully with the provisions of 42 U.S.C. § 290dd-2 and 42 CFR Part 2 and HIPAA 45 CFR parts 160 and 164;

8.1.1.1.5 Update each record within twenty-four (24) hours of delivery of a service unless otherwise specified in these regulations.

8.1.1.2 Any program that discontinues operations, or is merged with, or acquired by another program is responsible for ensuring compliance with the requirements of 42 CFR § 2.19, and HIPAA 45 CFR parts 160 and 164 whichever is applicable. The program shall document in writing to the Division:

8.1.1.2.1 How it will adhere to 42 CFR § 2.19 and HIPAA 45 CFR parts 160 and 164 at the time it notifies the Division of the program closure in accordance with §4.10.5 of these regulations; and

8.1.1.2.2 How it will adhere to §8.0 of these regulations.

8.1.2 Content of Client records

8.1.2.1 A record shall be established for each client upon admission and shall include:

8.1.2.1.1A Consent to Treatment form signed by the client and, if the client is a minor, the client's parent or guardian, except as provided in 16 ~~Del.C.~~ §2210(b).

8.1.2.1.2An up-to-date face sheet including the client's:

8.1.2.1.2.1 Date of admission;

8.1.2.1.2.2 Name;

8.1.2.1.2.3 Address;

8.1.2.1.2.4 Telephone number;

8.1.2.1.2.5 Gender;

8.1.2.1.2.6 Date of birth;

8.1.2.1.2.7 The client's significant medical history documenting:

8.1.2.1.2.7.1 Current medical conditions;

8.1.2.1.2.7.2 Any medications the client is currently prescribed;

8.1.2.1.2.7.3 Any medications the client is currently taking;

8.1.2.1.2.7.4 Allergies;

8.1.2.1.2.8 The name and telephone number of the person to contact in an emergency;

8.1.2.1.2.9 An attached Consent to Release Information form permitting the program to make that contact;

8.1.2.1.2.10 Name, address and telephone number of most recent primary care provider.

8.1.2.1.3 Appropriate Consent to Release Information forms.

8.1.2.1.4 Documentation, signed by the client:

8.1.2.1.4.1 Acknowledging receipt of the notice of clients' rights;

8.1.2.1.4.2 Acknowledging his/her understanding of the agency's agreement with the confidentiality requirements of §7.1.2.1.9;

8.1.2.1.4.3 Acknowledging receipt of the program's procedures when an emergency occurs outside of the program's hours of operation.

- 8.1.2.1.5Copies of any laboratory reports and drug tests ordered by the program.
- 8.1.2.1.6Informed consent regarding prescribed pharmacotherapy obtained from the client prior to delivery of the medication prescription.
- 8.1.2.1.7Results of the client's diagnostic assessment, including the client's:
 - 8.1.2.1.7.1Mental health status;
 - 8.1.2.1.7.2Psychiatric history;
 - 8.1.2.1.7.3Medical history (including allergies);
 - 8.1.2.1.7.4Education;
 - 8.1.2.1.7.5Work history;
 - 8.1.2.1.7.6Criminal justice history;
 - 8.1.2.1.7.7Substance use history, including:
 - 8.1.2.1.7.7.1Types;
 - 8.1.2.1.7.7.2Quantity;
 - 8.1.2.1.7.7.3Route;
 - 8.1.2.1.7.7.4Frequency of substances used;
 - 8.1.2.1.7.7.5Age of first use;
 - 8.1.2.1.7.7.6Date of last use;
 - 8.1.2.1.7.7.7Duration and patterns of use, including:
 - 8.1.2.1.7.7.7.1Periods of abstinence;
 - 8.1.2.1.7.8Past supports and resources that were effective in previous recovery attempts;
 - 8.1.2.1.7.9Previous treatment episodes and type of discharge;
 - 8.1.2.1.7.10Reason(s) for seeking treatment;
 - 8.1.2.1.7.11Identification and evaluation of the client's needs;
 - 8.1.2.1.7.12History of other addictive disorders.
 - 8.1.2.1.7.13Family History including:
 - 8.1.2.1.7.13.1Psychiatric history;
 - 8.1.2.1.7.13.2Use of alcohol and other drugs by family members and significant others.
 - 8.1.2.1.7.14A diagnostic assessment summary of the client's status that addresses the client's:
 - 8.1.2.1.7.14.1strengths;
 - 8.1.2.1.7.14.2barriers to treatment; and
 - 8.1.2.1.7.14.3goals.
 - 8.1.2.1.7.15Indicates which what issues and areas of clinical concern are to be:
 - 8.1.2.1.7.15.1Treated;
 - 8.1.2.1.7.15.2Deferred; or
 - 8.1.2.1.7.15.3Referred.
 - 8.1.2.1.7.16Includes the client's:
 - 8.1.2.1.7.16.1Primary language;
 - 8.1.2.1.7.16.2Cultural background;
 - 8.1.2.1.7.16.3Attitudes toward alcohol and other drug use; and
 - 8.1.2.1.7.16.4Spiritual or religious beliefs.
 - 8.1.2.1.7.17The rationale for placement recommendations:
 - 8.1.2.1.7.17.1Signed by the Counselor completing the assessment;
 - 8.1.2.1.7.17.2Reviewed, as indicated by the signature of the clinical supervisor; and
 - 8.1.2.1.7.17.3Is completed prior to the development of the initial Recovery Plan.
 - 8.1.2.1.7.18Copies of all correspondence related to the client.
- 8.1.2.1.8An individualized Recovery Plan, developed in partnership with the client, shall be completed no later than the time required in these regulations for the modality for which the program is licensed.
- 8.1.2.1.9The recovery plan shall:
 - 8.1.2.1.9.1Identify the date the plan is to be effective;
 - 8.1.2.1.9.2Identify the client's:
 - 8.1.2.1.9.2.1Strengths;

- 8.1.2.1.14.2 The narrative discharge summary shall include the client's:
 - 8.1.2.1.14.2.1 Name;
 - 8.1.2.1.14.2.2 Discharge address;
 - 8.1.2.1.14.2.3 Discharge telephone number;
 - 8.1.2.1.14.2.4 Admission date;
 - 8.1.2.1.14.2.5 Discharge date;
 - 8.1.2.1.14.2.6 A summary of the client's progress toward treatment plan objectives;
 - 8.1.2.1.14.2.7 A summary of the client's participation in treatment;
 - 8.1.2.1.14.2.8 The reasons for discharge;
 - 8.1.2.1.14.2.9 Any unresolved issues;
 - 8.1.2.1.14.2.10 Recommendations regarding the need for additional treatment services.
- 8.1.2.1.14.3 When the discharge is planned, the discharge summary shall be signed by:
 - 8.1.2.1.14.3.1 The client
 - 8.1.2.1.14.3.2 The counselor, and
 - 8.1.2.1.14.3.3 The clinical supervisor.

8.1.3 Programs shall provide a list of referral sources for the client's various needs when the agency is unable to meet the client's needs internally. The agency shall be responsible for assisting the client in enrolling in services at other agencies.

8.1.4 Programs shall provide a minimum of twelve (12) months of records up until and including the expiration date of the current license for the purposes of licensure audit. Programs shall develop a policy that clearly outlines timelines for record retention and storage for all records beyond the required audit period.

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9.0 Standards Applicable to all Facilities and Programs

9.1 Facility Standards

9.1.1 Unless otherwise specified programs shall be in compliance with the regulations in this section.

9.1.2 Each agency shall provide facilities that:

- 9.1.2.1 Provide privacy of for communications between clients and staff members;
- 9.1.2.2 Provide waiting areas and meeting spaces that are welcoming to diverse populations and cultures;
- 9.1.2.3 Include rest rooms for clients, visitors and staff.

9.1.3 Agencies shall maintain up to date documentation verifying that they have a certificate of occupancy and meet applicable federal, state and local building, zoning, fire, and safety and accessibility requirements.

9.1.4 Agencies shall maintain facilities in neat and clean condition, and eliminate any hazardous conditions that endanger the health or safety of clients, visitors or staff.

9.1.5 Agencies shall not permit tobacco use in program facilities.

9.1.6 Agencies shall post a current fee schedule in a public place within the facility.

9.1.7 Agencies shall post hours of operation in a public place within the facility.

9.2 Fire Prevention and Safety

9.2.1 Agencies shall display up to date certificates or approval/inspection by Fire Department authorities whenever this is required/available in the specific community where the program is located.

9.3 Emergency policies and procedures.

9.3.1 Each agency shall establish a plan of action in the event of emergencies or disasters, based on the program's capability and limitations. The plan shall include provisions:

- 9.3.1.1 For responding to severe weather, loss of power or water or other natural disaster;
 - 9.3.1.2 For evacuation plans with specific primary and alternative evacuation routes;
 - 9.3.1.3 For posting evacuation routes in areas visible to staff, clients and visitors;
 - 9.3.1.4 For responding to accidents that result in injury or death;
 - 9.3.1.5 Governing how available resources will be used to continue client care;
 - 9.3.1.6 Governing how the program will effectively activate community resources to prevent or minimize the consequences of a disaster;
 - 9.3.1.7 Concerning staff preparedness and the designation of roles and functions;
 - 9.3.1.8 Concerning criteria for the cessation of nonessential services and client transfer determinations;
- and

- 9.3.1.9 Governing how it will protect the safety of clients and staff and the security of its records.
- 9.3.2 All treatment programs shall develop procedures for handling a client who is exhibiting behavior that is threatening to the life or safety of the client or others.
- 9.3.3 All treatment programs shall have a staff member on site at all times trained in:
 - 9.3.3.1 Crisis intervention; and
 - 9.3.3.2 The standard Red Cross first aid class and CPR certification, or its equivalent.

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Part III--Provisions Regarding Modalities

10.0 Standards Applicable to Residential Detoxification

- 10.1 Services Required:
 - 10.1.1 In addition to the requirements applicable to all programs, a Medically Monitored Residential Detoxification program shall provide:
 - 10.1.1.1 Meals in accordance with §12.3.
 - 10.1.1.2 Housing in accordance with §12.4.
 - 10.1.1.3 Admission assessment by qualified medical personnel or licensed nurse prior to admission to determine need for detoxification.
 - 10.1.2 There shall be no administration of prescription or non-prescription drugs until qualified medical personnel have examined the client, or qualified medical personnel have been consulted.
 - 10.1.3 Physical examination conducted by qualified medical personnel within twenty-four (24) hours of admission.
 - 10.1.4 A medical care plan within twenty-four (24) hours of admission based on the findings of the physical examination in §10.1.3 and including:
 - 10.1.4.1 A brief screening to identify:
 - 10.1.4.1.1 Motivation for treatment;
 - 10.1.4.1.2 Relapse potential;
 - 10.1.4.1.3 Recovery environment at discharge.
 - 10.1.5 Within Seventy-two (72) hours of admission, diagnostic assessment in accordance with §8.1.2.1.7.
 - 10.1.6 Within seventy-two (72) hours of admission, recovery planning in accordance with §8.1.2.1.8.
 - 10.1.7 Periodic recovery plan review/revision in accordance with §8.1.2.1.10.
 - 10.1.7.1 By the seventh (7th) day, and
 - 10.1.7.2 Every fifth (5th) day thereafter.
 - 10.1.8 For those clients not medically restricted individual counseling that shall include at least one (1) fifteen (15) minute counseling contact per day with a Counselor I or Counselor II.
 - 10.1.9 Group counseling that shall include at least one (1) sixty-minute (60) counseling session per day with a Counselor I or Counselor II.
 - 10.1.10 Emergency medical and hospital services at a licensed hospital, as needed.
- 10.2 Required Additional Policies and Procedures
 - 10.2.1 The program shall have protocols developed and supported by a physician knowledgeable in addiction medicine setting forth:
 - 10.2.1.1 A medication policy that complies with §5.1.4.4.1.10.
 - 10.2.1.2 The protocol staff should take to respond to medical complications throughout the detoxification process.
 - 10.2.1.3 The circumstances under which medical intervention is required.
- 10.3 Operation, Staffing and Staff Schedules
 - 10.3.1 The program shall operate seven (7) days per week, twenty-four (24) hours per day.
 - 10.3.2 The program shall have written affiliation agreements for the provision of services required by this section, when those services are not provided in house.
 - 10.3.3 A physician(s) shall provide on-site services as necessary and on-call services twenty-four (24) hours a day.
 - 10.3.4 When clients are present, there shall be qualified medical personnel or a licensed nurse on-site who has knowledge of the complications associated with withdrawal.
 - 10.3.5 When clients are present, there shall be staff on duty and awake at all times.

10.3.6 A counselor shall be available on site to clients at least eight (8) hours a day, seven (7) days a week and available on call twenty four (24) hours a day.

10.4 Monitoring and documenting the client's condition

10.4.1 Upon admission, the program shall record:

10.4.1.1 Client's blood pressure;

10.4.1.2 Client's pulse;

10.4.1.3 Client's respiration;

10.4.1.4 Presence of bruises, lacerations, cuts or wounds;

10.4.1.5 Any medications carried by the client or found on the client's person.

10.4.1.6 Documentation, at a frequency prescribed by Qualified Medical Personnel, but no less than three times in the first eight hours after admission of:

10.4.1.6.1 Blood Pressure;

10.4.1.6.2 Pulse;

10.4.1.6.3 Respiration;

10.4.1.6.4 Type and amount of fluid intake;

10.4.1.6.5 Physical state, including the presence of tremors, ataxia, or excessive perspiration, restlessness, and sleep disturbances;

10.4.1.6.6 Mental state, including the presence of confusion, hallucinations, and orientation to person, place, and time;

10.4.1.6.7 Emotional state, including the presence of anxiety, depression.

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11.0 Standards Applicable to Ambulatory Detoxification (Amdetox):

In addition to these standards, all programs providing Amdetox services shall be in full compliance with Federal Regulations regarding the dispensing and handling of all medications used in the detoxification of substance use disorders.

11.1 Services Required

11.1.1 In addition to the requirements applicable to all programs, an Amdetox program shall provide:

11.1.1.1 An initial screening, documentation of which shall include:

11.1.1.1.1 Verification of an applicant's identity, including:

11.1.1.1.1.1 Name;

11.1.1.1.1.2 Address;

11.1.1.1.1.3 Date of birth; and

11.1.1.1.1.4 Photographic identification.

11.1.1.1.2 Determination of current physiologic dependence and/or history of dependence upon opium, morphine, heroin or any derivative or synthetic drug of that group, in accordance with DSM criteria, by medical examination performed by qualified medical personnel.

11.1.1.1.3 Determination of current physiologic dependence and/or history of dependence on alcohol or other substances known to result in physical dependence in accordance with DSM criteria.

11.1.1.1.3.1 Documentation to support that determination shall include:

11.1.1.1.3.1.1 Qualified medical personnel statement that treatment is medically necessary;

11.1.1.1.3.1.2 The five-axis DSM diagnosis (most current DSM edition);

11.1.1.1.3.1.3 A description of behavior(s) supportive of a diagnosis of dependence;

11.1.1.1.3.1.4 Determination of the duration of substance dependence.

11.1.1.1.3.2 A physical examination by qualified medical personnel that shall:

11.1.1.1.3.2.1 Include documentation of the client's general appearance with a focus on the clinical signs and symptoms of addiction;

11.1.1.1.3.2.2 Document vital signs;

11.1.1.1.3.2.3 Include a complete medical history;

11.1.1.1.3.2.4 Include the client's family medical history;

11.1.1.1.3.2.5 Include medications currently being taken; and

11.1.1.1.3.2.6 Completed at admission.

- ~~11.1.1.1.3.3 Determination by qualified medical personnel that the person's history and current symptomatology support Amdetox as the most appropriate level of care.~~
- ~~11.1.1.1.4 Laboratory tests including serology and other tests deemed necessary by the program physician.~~
- ~~11.1.1.1.5A biological test for pregnancy for all women of child-bearing age.~~
- ~~11.1.1.1.6 HIV testing should be encouraged, with the client's signed consent.~~
- ~~11.1.1.2 A client enrolled in an Opioid Treatment program or another Amdetox program shall not be permitted to enroll in treatment in any other Amdetox program except in exceptional circumstances as determined by the medical director. Exceptions shall be:~~
 - ~~11.1.1.2.1 Noted in the client's record.~~

11.2 Admission procedures

~~11.2.1 In addition to the procedures described in §8.1.2, Amdetox programs shall provide:~~

- ~~11.2.1.1 A medical care plan within twenty-four (24) hours of admission based on the findings of the physical examination in §11.1.1.1.3.2.~~
- ~~11.2.1.2 Diagnostic assessment in accordance with §8.1.2.1.7 within twenty-four (24) hours of admission.~~
 - ~~11.2.1.2.1 An Initial Recovery Plan as derived by the diagnostic assessment in §11.2.1.7 of these standards and the medical care plan in §11.2.1.1 of these standards within twenty-four (24) hours of admission.~~
 - ~~11.2.1.2.2 Recovery plan updates/revisions shall occur:~~
 - ~~11.2.1.2.2.1 As needed based on the changes of intensity level of treatment for each client and:~~
 - ~~11.2.1.2.2.1.1 No later than the seventh (7h) day; AND~~
 - ~~11.2.1.2.2.1.2 Every seven (7) days thereafter.~~
- ~~11.2.1.3 Procedures for referral to a licensed hospital or residential detoxification program when a more or less intensive level of care is indicated.~~

11.3 Client Orientation

~~11.3.1 In addition to the requirements of §8.1.2.1.4 the Amdetox program shall inform clients of:~~

- ~~11.3.1.1 The facts concerning the use of buprenorphine, naltrexone, chlordiazepoxide or other detoxification medications dispensed by the program, including, but not limited to:~~
 - ~~11.3.1.1.1 An explanation of the interaction between the detoxification medication(s) dispensed by the program and other medications, and medical procedures;~~
 - ~~11.3.1.1.2 Any potential adverse reactions, including those resulting from interactions with other prescribed or over-the-counter pharmacological agents, other medical procedures; and~~
 - ~~11.3.1.1.3 The importance of notifying the client's primary care physician of their admission to and discharge from the program.~~
- ~~11.3.1.2 The facts concerning withdrawal from the use of, buprenorphine, naltrexone, chlordiazepoxide or other detoxification medications dispensed by the program, including, but not limited to:~~
 - ~~11.3.1.2.1 Policies and procedures regarding voluntary, involuntary, and against medical advice withdrawal from detoxification medications;~~
 - ~~11.3.1.2.2 An explanation of the potential interaction between withdrawal from the detoxification medication(s) dispensed by the program and other medications, medical procedures and;~~
 - ~~11.3.1.2.3 Any potential adverse reactions as a result of withdrawal from detoxification medications, including those resulting from interactions with other prescribed or over-the-counter pharmacological agents, other medical procedures; and~~
 - ~~11.3.1.2.4 The importance of notifying the client's primary care physician of withdrawal from the program.~~

11.4 Clinical Services

~~11.4.1 In addition to the requirements of §8.0 the Amdetox program shall provide:~~

- ~~11.4.1.1 Individual counseling that shall include at least one (1) sixty (60) minute counseling session per week by a Counselor I or Counselor II.~~
- ~~11.4.1.2 Daily counseling contact by a Counselor I or Counselor II that shall include at a minimum:-~~
 - ~~11.4.1.2.1 One (1) fifteen (15) minute face-to-face or phone contact to:~~
 - ~~11.4.1.2.1.1 Engage the client;~~
 - ~~11.4.1.2.1.2 Help the client cope with withdrawal; and~~
 - ~~11.4.1.2.1.3 Continue in ongoing treatment services.~~
 - ~~11.4.1.2.2 Group Counseling that shall include at least two (2) ninety (90) minute counseling session per week.~~

~~11.4.1.2.3The discharge plan outlined in §8.1.2.1.13 and discharge summary outlined in §8.1.2.1.14 of these standards.~~

~~11.4.1.2.4Referral to a more or less intensive level of care as outlined in §8.1.3 of these standards.~~

11.5 Administrative Procedures

11.5.1 In addition to the requirements of §4.0 of these standards the Amdetox program shall develop policies and procedures that describe:

11.5.1.1 The program's medical/nursing monitoring schedule including:

~~11.5.1.1.1Monitoring on the first day to determine the response to detoxification medication;~~

~~11.5.1.1.2Monitoring of vital signs throughout the detoxification process;~~

~~11.5.1.1.3Monitoring of symptom history within the most recent 24 hours.~~

11.5.1.2 The program's drug screening procedure;

11.5.1.3 The program's Amdetox medication dispensing procedure;

11.5.1.4 The program's rules including non-compliance, and discharge procedures, to include:

~~11.5.1.4.1Administrative detoxification medication withdrawal;~~

~~11.5.1.4.2The signs and symptoms of overdose; and~~

~~11.5.1.4.3When to seek emergency assistance.~~

11.5.1.5 The emergency procedures maintained by the program as required in §5.1.4.4.1.21 shall be available whenever clients are present at the program.

11.5.1.6 The program shall have protocols developed and supported by a physician knowledgeable in addiction medicine setting forth:

~~11.5.1.6.1The requirement for qualified staff to obtain waivers allowing qualified physicians to dispense or prescribe specifically approved Schedule III, IV, and V narcotic medications for the treatment of Opioid addiction in treatment settings other than the traditional Opioid Treatment Program (i.e., methadone clinic) in accordance with the Drug Addiction Treatment Act of 2000 (DATA 2000.)~~

11.5.1.6.2A medication policy that complies with §5.1.4.4.1.19 and includes:

11.5.1.6.2.1 Induction protocols and policies for:

~~11.5.1.6.2.1.1Day one (1) and day two (2) of Opioid detoxification;~~

~~11.5.1.6.2.1.2Day three (3) of Opioid detoxification and forward.~~

11.5.1.6.2.2 Induction protocols and policies for all other medications used in detoxification.

11.5.1.6.2.3 Stabilization that includes:

~~11.5.1.6.2.3.1Documentation and rationale for changes in medication dosage;~~

~~11.5.1.6.2.3.2Average length of stay criteria; and~~

~~11.5.1.6.2.3.3Criteria for linkage to outpatient treatment.~~

11.5.1.6.2.4 Protocols for the decrease and/or discontinuance of detoxification medications to include:

~~11.5.1.6.2.4.1Protocols for decreasing or discontinuing detoxification meds when the client requests;~~

~~11.5.1.6.2.4.2Protocols for decreasing or discontinuing when the program determines that maximum benefit has been achieved; and~~

~~11.5.1.6.2.4.3Protocols for decreasing or discontinuing when being administratively discharged or if the client chooses no further treatment.~~

11.5.1.6.2.5 The protocol staff should follow to respond to medical complications throughout the detoxification process.

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12.0 Residential Treatment

12.1 Services Required

12.1.1 In addition to the requirements applicable to all programs, a Residential Treatment program shall provide:

12.1.1.1 Medical assessment by qualified medical personnel on the day of admission.

12.1.1.2 A physical examination in accordance with §8.1.2.1.2.1.7 within seventy two (72) hours of admission, unless the client presents a copy of a physical examination completed by qualified medical personnel within ninety (90) days prior to admission.

12.1.1.3 A TB test and urine drug screen within seventy two (72) hours of admission or documentation of a TB test performed within one (1) year prior to admission.

- 12.1.1.4 RESERVED
- 12.1.1.5 Diagnostic assessment in accordance with 8.1.2.1.7 within forty-eight (48) hours of admission.
- 12.1.1.6 The recovery plan required by §8.1.2.1.8 within seventy-two (72) hours of admission.
- 12.1.1.7 Recovery plan review/revision and update in accordance with §8.1.2.1.10 as needed based on changes in functioning for each client and at a minimum:
 - 12.1.1.7.1 On the thirtieth (30) day; and
 - 12.1.1.7.2 Every thirty (30) days thereafter.

12.2 Hours of Operation, Staffing and Staff Schedules

- 12.2.1 Residential programs shall operate twenty-four (24) hours per day, seven (7) days per week.
- 12.2.2 There shall be staff on duty and awake at all times.
- 12.2.3 A counselor shall be on site at least eight (8) hours a day, seven (7) days a week and available on call twenty-four (24) hours a day.
- 12.2.4 Counselor I's and Counselor II's shall meet face-to-face with clinical supervisors a minimum of one (1) hour per Counselor per week for clinical supervision.

12.3 Nutritional Services

- 12.3.1 Programs shall establish a written plan for meeting the basic nutritional needs, as well as any special dietetic needs, of clients. Plans shall:
 - 12.3.1.1 Include a varied and nutritious diet of at least three (3) meals a day, seven (7) days per week;
 - 12.3.1.2 Include snacks as part of the overall dietary plan;
 - 12.3.1.3 Include food substitutions, (as applicable);
 - 12.3.1.4 Be reviewed by a registered dietitian annually and when they are changed.

12.4 Facility Standards

- 12.4.1 All residential programs shall provide:
 - 12.4.1.1 Separation of sleeping quarters serving male and female clients;
 - 12.4.1.2 Separation of bathroom facilities serving male and female clients;
 - 12.4.1.3 Privacy for personal hygiene;
 - 12.4.1.4 Secure closet and storage space for clients' personal property;
 - 12.4.1.5 Security for valuables, including an inventory and receipt system;
 - 12.4.1.6 Laundry facilities for clients; and
 - 12.4.1.7 Space for solitude.
- 12.4.2 All agencies operating residential programs shall ensure that in addition to the clients' rights enumerated in §7.0, these additional clients' rights are fully protected:
 - 12.4.2.1 The right to visitation with family and friends, subject to written visiting rules and hours established by the program, except as provided in this subsection.
 - 12.4.2.2 The right to conduct private telephone conversations, subject to written rules and hours established by the program, except as provided in this subsection.
 - 12.4.2.2.1 The Administrator or designee may impose limitations on any of the, visitation and/or phone call procedures when in the judgment of the Administrator, such limitations are therapeutically necessary. Limitations shall be recorded in the client's record.
 - 12.4.2.3 The right to send and receive uncensored and unopened mail. Program may require the client to open mail or package(s) in the presence of program staff for inspection.
 - 12.4.2.4 The right to wear his/her own clothing subject to written program rules.
 - 12.4.2.5 The right to bring personal belongings, subject to limitation or supervision by the program.
 - 12.4.2.6 The right to communicate with their personal physician.
 - 12.4.2.7 The right to practice their personal religion or attend religious services, within the program's policies and written policies for attendance at outside religious services.

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13.0 Transitional residential treatment

13.1 Services Required

- 13.1.1 In addition to the requirements applicable to all programs, a Transitional residential treatment program shall provide:
 - 13.1.1.1 Meals in accordance with §12.3.

- ~~13.1.1.2 Housing in accordance with §12.4.~~
- ~~13.1.1.3 Physical examination by qualified medical personnel within seventy-two (72) hours of admission unless the client has had a physical examination completed by qualified medical personnel within ninety days (90) prior to admission.~~
- ~~13.1.1.4 Within seven (7) days of admission, diagnostic assessment in accordance with §8.1.2.1.7.~~
- ~~13.1.1.5 Within seven (7) days of admission, recovery planning in accordance with §8.1.2.1.8.~~
- ~~13.1.1.6 Recovery plan review/revision in accordance with §8.1.2.1.9 as needed based on changes in functioning for each client and at a minimum:

 - ~~13.1.1.6.1 Every thirty (30) days.~~
 - ~~13.1.1.7 Medical evaluation and consultation by a licensed physician, as needed.~~
 - ~~13.1.1.8 Emergency medical and hospital services at a licensed hospital, as needed.~~~~
- ~~13.1.2 Operation, Staffing and Staff Schedules

 - ~~13.1.2.1 The program shall operate twenty four (24) hours per day, seven (7) days per week.~~
 - ~~13.1.2.2 The program shall have written affiliation agreements for the provision of services required by the recovery plan in §8.1.2.1.9.3.2.5.3 of these standards, when these services are not provided in house.~~
 - ~~13.1.2.3 When clients are present, there shall be staff on site and on duty at all times.~~
 - ~~13.1.2.4 A Counselor shall be available to clients twenty four (24) hours a day, seven (7) days per week.~~~~

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14.0 Opioid Treatment Services:

In addition to these standards, all programs providing Opioid treatment services shall be in full compliance with Federal Regulations regarding Opioid treatment.

- ~~14.1 Admission procedures in addition to the admission procedures described in §8.1.2:

 - ~~14.1.1 If an applicant for Opioid treatment services has been discharged within seven (7) years from treatment at another OTP, the admitting program shall document that a good faith effort was made to review whether or not the client is enrolled in any other OTP.~~
 - ~~14.1.2 A client enrolled in another program shall not be permitted to enroll in treatment in any other OTP except in exceptional circumstances as determined by the medical director. Exceptions shall be:

 - ~~14.1.2.1 Noted in the client's record.~~~~~~
- ~~14.2 Special admission populations (where the absence of physiological dependence shall not be an exclusion criterion with a clinically justifiable admission) shall include:

 - ~~14.2.1 Persons recently released from a penal institution; (within six (6) months after release.)~~
 - ~~14.2.2 Pregnant clients; (Program physician shall certify pregnancy)~~
 - ~~14.2.3 Previously treated clients; (Up to two (2) years after discharge)~~
 - ~~14.2.4 Adolescents, provided that:

 - ~~14.2.4.1 Individuals under the age of 18 have had two documented attempts at short-term medically supervised withdrawal (detoxification) or drug-free treatment to be eligible for maintenance treatment;~~
 - ~~14.2.4.2 In addition to the consent of the client, Individuals under 18 years old, unless otherwise permitted by 16 Del.C. §2210 to consent to treatment, have had a parent or legal guardian complete and sign the agency's consent to OTP Treatment.~~~~~~
- ~~14.3 Client Orientation

 - ~~14.3.1 In addition to the requirements of §8.1.2.1.4 OTPs shall inform clients of:

 - ~~14.3.1.1 The facts concerning the use of methadone, buprenorphine, or other Opioid treatment medications dispensed by the program, including, but not limited to:

 - ~~14.3.1.1.1 An explanation of the interaction between the Opioid treatment medication(s) dispensed by the program and other medications, medical procedures and food;~~
 - ~~14.3.1.1.2 Any potential adverse reactions, including those resulting from interactions with other prescribed or over-the-counter pharmacological agents, other medical procedures and food; and~~
 - ~~14.3.1.1.3 The importance of notifying the client's primary care physician of their admission to and discharge from the program;~~~~~~~~

- 14.3.1.1.4 ~~The facts concerning the withdrawal from the use of methadone, buprenorphine, or other Opioid treatment medications dispensed by the program, including, but not limited to:~~
- 14.3.1.1.5 ~~Policies and procedures regarding voluntary, involuntary, and against medical advice withdrawal from Opioid treatment medications;~~
- 14.3.1.1.6 ~~An explanation of the potential interaction between withdrawal from the Opioid treatment medication(s) dispensed by the program and other medications, and medical procedures;~~
- 14.3.1.1.7 ~~Any potential adverse reactions as a result of withdrawal from Opioid treatment medications, including those resulting from interactions with other prescribed or over-the-counter pharmacological agents, other medical procedures; and~~
- 14.3.1.1.8 ~~The importance of notifying the client's primary care physician of withdrawal from the program.~~
- 14.3.1.2 The program's drug screening procedure;
- 14.3.1.3 The program's Opioid treatment medication dispensing procedure, including the days and hours of operation;
- 14.3.1.4 The program's rules including non-compliance, and discharge procedures, to include administrative Opioid treatment medication withdrawal;
- 14.3.1.5 The signs and symptoms of overdose and when to seek emergency assistance;
- 14.3.1.6 The emergency procedures maintained by the program as required in §5.1.4.4.1.21 shall be available twenty-four (24) hours per day.
- 14.3.1.7 Safe storage practices for take-home Opioid treatment medications;
- 14.3.1.8 The financial aspects of treatment, including the consequences of nonpayment of required fees.
- 14.3.2 Upon admission, the program shall obtain from or issue to each client a photo identification card.
- 14.4 ~~Client Re-admissions-~~
- 14.4.1 ~~A client re-admitted to the same program within thirty (30) days need not receive a medical examination and laboratory tests if s/he received a medical examination and laboratory tests within the previous year.~~
- 14.5 ~~Hours of Operation, Staffing, and Staff Orientation~~
- 14.5.1 ~~OTPs shall operate six (6) days per week, with at least two (2) hours of medicating time accessible daily outside the hours of 8 a.m. to 5 p.m. Monday through Friday, and three (3) hours on Saturday or Sunday.~~
- 14.5.2 ~~Each OTP shall post medication dispensing and counseling hours in a public place within the facility.~~
- 14.5.3 ~~Each OTP shall have the services of licensed medical personnel including:~~
- 14.5.3.1 ~~A designated medical director, who is a physician, responsible for the administration of all medical services performed by the program and for compliance with all federal, state and local laws, rules and regulations regarding medical treatment of narcotic dependence;~~
- 14.5.3.2 ~~At all times when the clinic is open, if a physician is not on site, a physician shall be available for consultations and emergency attendance;~~
- 14.5.3.3 ~~Prior to services delivery, in addition to training requirements in §5.1.7.1, OTPs shall provide new staff orientation, including:~~
- 14.5.3.3.1 ~~Clinical and pharmacotherapy issues,~~
- 14.5.3.3.2 ~~Overdose, and other emergency procedures,~~
- 14.5.3.3.3 ~~Provision of services to special populations such as adolescents, pregnant women, and senior citizens.~~
- 14.6 ~~Administration of Opioid treatment medication~~
- 14.6.1 ~~No dose of Opioid treatment medication shall be administered until the client has been identified and the dosage compared with the currently ordered and documented dosage level.~~
- 14.6.2 ~~Only a licensed professional authorized by law may administer or dispense Opioid treatment medication.~~
- 14.6.3 ~~Ingestion shall be observed and verified by the personnel authorized to administer the Opioid treatment medication.~~
- 14.6.4 ~~There shall be only one client in the dispensing area at a time.~~
- 14.6.5 ~~A physician shall obtain a detailed history of drug use within the last twenty-four (24) hours prior to initial dose, and,~~
- 14.6.5.1 ~~Determine the client's initial dosage after a physical examination;~~
- 14.6.5.2 ~~The initial dose of Methadone shall not exceed thirty (30) mg.;~~
- 14.6.5.3 ~~Additional medication shall not be administered, unless:~~

- 14.6.5.3.1After three (3) hours of observation, the physician documents in the client's record that the initial dose did not suppress opiate abstinence symptoms; and
- 14.6.5.3.2The physician writes orders for additional medication.
- 14.6.5.4 The initial total daily dose of methadone for the first day shall not exceed forty (40) mg., unless the physician documents justification for a higher dosage in the client record that forty (40) mg did not suppress opiate abstinence symptoms.
- 14.6.5.5 The initial dose of any other Opioid treatment medications shall not exceed federal regulations, guidelines or medical protocol.
- 14.6.5.6 The program physician shall justify any deviations from dosages, frequencies, and conditions of usage described in the approved product labeling.
- 14.6.5.7 Qualified medical personnel shall determine all subsequent dosage levels and shall:
 - 14.6.5.7.1Document each order change on the physician's medication orders;
 - 14.6.5.7.2Sign each order change; and
 - 14.6.5.7.3Date the order.
- 14.6.5.8 Programs shall dispense methadone in an oral form, in accordance with federal and state law and regulations in containers conforming to 42 CFR (Part VIII) Section 12.(i)(5).
- 14.6.5.9 Any Opioid treatment medication error or adverse drug reaction shall be reported promptly to the medical director and an entry made in the client's record.
- 14.6.5.10 The medical director shall ensure that significant adverse drug reactions are reported to the Federal Food and Drug Administration and to the manufacturer in a manner that does not violate the client's confidentiality.
- 14.6.5.11 Each program shall develop a written emergency procedure to be implemented in the case of an employee strike, fire or other emergency situation that would stop or substantially interfere with normal dispensing operations. The emergency procedure shall comply with 9.3 and also include:
 - 14.6.5.12 Arrangements with a security provider for immediate security of Opioid treatment medications;
 - 14.6.5.13 Written agreements, updated annually, with back-up licensed professionals authorized by law, for the coverage of dispensing and other medical needs if regular personnel are not available;
 - 14.6.5.14 A reliable system for confirming the identities of clients before dispensing; and
 - 14.6.5.15 Written agreements, updated annually, for the use of an alternate program, hospital or other site for dispensing during an emergency period.
- 14.7 Opioid treatment medication schedules; Unsupervised or "take-home use":
 - 14.7.1 Treatment program decisions on dispensing unsupervised or "take-home" medications shall be determined by the medical director. The medical director shall consider the following criteria to determine whether a patient is responsible in handling drugs for unsupervised use:
 - 14.7.1.1 Regularity of program attendance;
 - 14.7.1.2 Absence of recent abuse of drugs, including alcohol;
 - 14.7.1.3 Regularity of clinic attendance;
 - 14.7.1.4 Absence of serious behavioral problems at the clinic.
 - 14.7.1.5 Absence of known recent criminal activity (e.g. drug and drug related arrests, etc...)
 - 14.7.1.6 Progress in meeting treatment plan goals;
 - 14.7.1.7 Length of time in treatment;
 - 14.7.1.8 Responsibility in the handling, and plan for the safe storage, of take home Opioid treatment medications;
 - 14.7.1.9 Stability of the client's home environment and social relationships.
 - 14.7.1.10 When it is determined that a patient is responsible in handling Opioid drugs, the Federal Regulations for take home privileges shall be applied.
 - 14.7.1.11 OTPs shall maintain current procedures adequate to identify the theft or diversion of take-home medications, including:
 - 14.7.1.11.1labeling containers with the OTP's name, address, and telephone number; and
 - 14.7.1.11.2requiring patients to come to the clinic on a randomly scheduled basis for drug testing and checking the amount of take-home medication used to that point.
 - 14.7.1.12 Programs shall also ensure that take-home supplies are packaged in a manner that is designed to reduce the risk of accidental ingestion, including child-proof containers.
- 14.8 Revocation of take-home privileges.

14.8.1 The program medical director will determine if a client's conduct warrants revocation or suspension of take-home privileges.

14.8.2 Documentation of the rationale for revoking or suspending take-home privileges will be entered into the client's record by the medical director.

14.9 Exceptions.

14.9.1 If, in the judgment of the program physician:

14.9.1.1 A client has a physical disability that interferes with his or her ability to conform to the applicable mandatory attendance schedule, the program physician may permit a reduced attendance schedule.

14.9.1.2 A client is unable to conform to the applicable mandatory attendance schedule because of exceptional circumstances such as illness, personal or family crises, travel, or other hardship, the program physician may permit a temporarily reduced schedule, provided that the client is responsible in handling Opioid treatment medications. In such cases, the program physician shall record or verify the rationale for the exception in the client's record and date and sign the record. No client may receive more than a two (2) week supply of Opioid treatment medication at any one time.

14.9.1.3 Employed clients may apply for an exception to these requirements if the dispensing hours of the clinic conflict with working hours of the client. In such cases, the client may receive take-home medications after verifying work hours through reliable means, provided that the physician documents reasons for permitting take home medication.

14.9.1.4 Any client who transfers from one (1) OTP to another shall be eligible for placement on the same take-home schedule. Before initiating take-home privileges for a client transferring from other maintenance treatment programs, the program physician shall document reasons for permitting take home medication.

14.10 Voluntary Medical withdrawal from Opioid treatment Medication

14.10.1 Voluntary medical withdraw from Opioid treatment medication shall include:

14.10.1.1 A request signed and dated by the client, for voluntary medication withdrawal.

14.10.1.2 Documentation of the physician's rationale for initiation of withdrawal.

14.10.1.3 Documentation of the physician's rationale for continuing the withdrawal if there is any change in the physician's orders.

14.10.1.4 Documentation signed and dated by the client that the withdrawal will be discontinued and maintenance resumed at the client's request.

14.10.1.5 A biological test for pregnancy for all women of child-bearing age prior to the initiation of withdrawal.

14.10.1.6 Revision of the treatment plan with an increase in counseling and other support services in relation to medication dosage changes.

14.10.1.7 Provisions for continuing care after the last dose of Opioid treatment medication.

14.11 Withdrawal against medical advice

14.11.1 Withdrawal against medical advice shall include:

14.11.1.1 Documentation of all efforts taken by staff members to discourage initiation and continuation of withdrawal against medical advice.

14.11.1.2 Documentation of the reasons the client is seeking withdrawal against medical advice.

14.11.2 Involuntary withdrawal:

14.11.2.1 Involuntary withdrawal from an Opioid treatment medication shall be conducted in accordance with a dosage reduction schedule prescribed by the physician.

14.11.2.2 Clients being involuntarily discharged shall be referred to other treatment, as clinically indicated.

14.11.2.3 OTPs shall document the reasons for initiation of involuntarily withdrawal in the client's record.

14.11.2.4 Prior to the beginning of involuntary withdrawal, efforts should be documented regarding referral or transfer of the client to a suitable, alternative treatment program.

14.11.2.5 Involuntary withdrawal shall be considered a planned discharge and shall comply with §8.6 regarding the planned discharge of a client.

14.11.2.6 Documentation during withdrawal shall include:

14.11.2.6.1 Documentation by the physician of the schedule for withdrawal and any changes made to the schedule by the physician during the withdrawal.

14.11.2.6.2 Counseling designed to promote the continuation of services following medical withdrawal.

14.11.3 Detoxification treatment

- 14.11.3.1 ~~An OTP shall maintain procedures that are designed to ensure that qualified medical personnel admit clients to short- or long-term detoxification treatment.~~
- 14.11.3.2 ~~Patients with two or more unsuccessful detoxification episodes within a twelve (12) month period shall be assessed by the OTP physician for other forms of treatment.~~
- 14.11.3.3 ~~A program shall not admit a client for more than two (2) detoxification treatment episodes in one year.~~

14.11.4 Pregnant Clients

- 14.11.4.1 ~~In addition to the other requirements of this section, for pregnant clients the following shall apply:~~
 - 14.11.4.1.1 ~~OTPs shall provide priority in initiating treatment.~~
 - 14.11.4.1.2 ~~The physician shall document in the client record all clinical findings supporting the certification of the pregnancy prior to the administration of an initial dose of Opioid treatment medication.~~
 - 14.11.4.1.3 ~~The initial dose of Methadone shall not exceed 40 mg.~~
 - 14.11.4.1.4 ~~The program physician shall evaluate dosing of pregnant women weekly during the last trimester of the pregnancy.~~
 - 14.11.4.1.5 ~~If there is simultaneous use of alcohol and/or other drugs the program shall document:~~
 - 14.11.4.1.5.1 ~~Education of the client regarding the potential impact of substance use on the fetus.~~
 - 14.11.4.1.5.2 ~~Attempts to encourage the client to cease use of substances other than those prescribed by a physician.~~
 - 14.11.4.1.5.3 ~~Referrals made to appropriate levels of care.~~
 - 14.11.4.1.6 ~~Pregnant clients shall be given the opportunity for prenatal care either by the program or by referral to appropriate health care providers.~~
 - 14.11.4.1.7 ~~The program shall document all attempts to assist the client with obtaining prenatal care.~~
 - 14.11.4.1.8 ~~The program shall offer prenatal instruction on:~~
 - 14.11.4.1.8.1 ~~Education on fetal development;~~
 - 14.11.4.1.8.2 ~~Care for the newborn;~~
 - 14.11.4.1.8.3 ~~Breastfeeding;~~
 - 14.11.4.1.8.4 ~~Effects of maternal drug use on the fetus;~~
 - 14.11.4.1.8.5 ~~Information on parenting;~~
 - 14.11.4.1.8.6 ~~Importance of sound maternal nutritional practices.~~
- 14.11.4.2 ~~OTP's shall give priority to pregnant women seeking admission to treatment.~~
- 14.11.4.3 ~~OTP's shall maintain current policies and procedures that reflect the special needs of patients who are pregnant. Prenatal and other gender specific services shall be provided either by the OTP or by referral to appropriate health care providers.~~
- 14.11.4.4 ~~Medical withdrawal of the pregnant, Opioid-addicted woman from Opioid treatment medication is not indicated or recommended. No pregnant client shall be involuntarily medically withdrawn from an Opioid treatment medication.~~
- 14.11.4.5 ~~Pregnant individuals who choose to withdraw from treatment against medical advice shall do so under the direct supervision of the program physician in conjunction with an obstetrician who can monitor the effects on the fetus.~~
- 14.11.4.6 ~~If a pregnant client refuses direct treatment, referral for treatment, or referral for other services, the program physician shall have the client acknowledge said refusal in writing. Documentation of the refusal shall be recorded in the client's record.~~
- 14.11.4.7 ~~The program physician shall request the physician, hospital, or program to which the individual is referred, to provide reports of prenatal care, and a summary of the delivery and treatment outcome for the client and baby. Documentation of the request(s) shall be included in the client's record.~~
- 14.11.4.8 ~~Within three (3) months after termination of the pregnancy, the program physician shall evaluate the individual's treatment status and document whether she should remain in the comprehensive maintenance program or be detoxified.~~

14.12 Accreditation

- 14.12.1 ~~Programs shall be accredited by an accreditation body approved by The Substance Abuse and Mental Health Services Administration (SAMSHA) and registered with the Drug Enforcement Agency (DEA), as required.~~

15.0 Outpatient Treatment

15.1 Services Required

15.1.1 In addition to the requirements applicable to all programs, an Outpatient Treatment program shall provide:

15.1.1.1 Documentation of a physical examination by qualified medical personnel within ninety (90) days prior to admission.

15.1.1.1.1 When documentation of a physical examination by qualified medical staff is not made available to the program, the program shall document a good faith effort in referring the client for a physical and/or efforts made to obtain documentation of a physical.

15.1.1.2 Diagnostic assessment in accordance with §8.1.2.1.7 within thirty (30) days of admission.

15.1.1.3 Recovery planning in accordance with §8.1.2.1.8 within thirty (30) days of admission or by the fourth (4th) counseling session, whichever occurs first.

15.1.1.4 Recovery plan review/revision in accordance with 8.1.2.1.10 as needed based on changes in functioning for each client and at a minimum:-

15.1.1.4.1 Every ninety (90) days after the effective date of the first treatment plan.

15.2 Any time that services are offered at locations other than the program's main building, the program will assure that all requirements of §9.0 of these regulations are met in full.

14 DE Reg. 471 (11/01/10)

16.0 Co-Occurring Treatment

16.1 In addition to the requirements applicable to all programs and §15.0 of these standards, a Co-Occurring Treatment program shall provide a cadre of staff and services to meet the psychiatric and substance use disorder needs of clients. Staffing shall be flexible and meet the changing needs of the population served.

16.2 Staffing

16.2.1 Qualifications for the Position of Medical Director

16.2.1.1 Each Medical Director shall be a person with a Medical Degree or Doctor of Osteopathy degree; licensed to practice medicine in the state of Delaware and has completed (or is enrolled in) an accredited residency training program in psychiatry, internal medicine or family practice.

16.2.2 Qualifications for the Position of Qualified Psychiatric Practitioner

16.2.2.1 Qualified Psychiatric Practitioners shall meet the criteria for Qualified Medical Personnel as defined in §3.0 of these standards; AND

16.2.2.2 Have a minimum of three (3) years of documented clinical experience in the field of mental health.

16.2.3 Qualifications for the Position of Clinical Director

16.2.3.1 Each individual hired or promoted to provide clinical supervision on or after the date these regulations become effective shall, at a minimum, meet the following criteria:

16.2.3.1.1A master's degree with a major in psychology, social work, counseling, nursing or a related field of study and six (6) years of clinical experience in human services, three (3) of which shall be in substance abuse treatment services; OR

16.2.3.1.2A master's degree from an accredited college or university with a major in chemical dependency, psychology, social work, counseling, nursing or a related field of study and full certification as a Certified Co-Occurring Disorders Professional in the state of Delaware (CGDP); OR

16.2.3.1.3A master's degree from an accredited college or university with a major in chemical dependency, psychology, social work, counseling, nursing or a related field of study and full certification as a Certified Co-Occurring Disorders Professional by a nationally recognized body.

16.2.3.2 Clinical supervisor as defined in §6.1.3 will not meet the criteria for Clinical supervisor for a co-occurring treatment program.

16.2.4 Qualifications for the Position of Mental Health Clinician

16.2.4.1 Each individual hired or promoted to the position of Mental Health Clinician on or after the date these regulations become effective shall meet the following criteria at a minimum:

16.2.4.1.1A master's degree in psychology, counseling, social work, nursing, rehabilitation or related field of study from an accredited college or university.

16.2.5 Qualifications for the Position of Associate Mental Health Clinician:

16.2.5.1 Each individual hired or promoted to the position of Associate Mental Health Clinician on or after the date these regulations become effective shall, at a minimum, meet the following criteria:

~~16.2.5.1.1 Full certification as a Certified Co-Occurring Disorders Professional in the state of Delaware (CCDP); OR~~

~~16.2.5.1.2 Full certification as a Certified Co-Occurring Disorders Professional by a nationally recognized body; OR~~

~~16.2.5.1.3A bachelor's degree from an accredited college or university in psychology, social work, counseling, or nursing and five (5) years of documented clinical experience working in the field of mental health~~

~~16.2.6 Qualifications for the position of Case Manager~~

~~16.2.6.1 Co-occurring treatment programs that employ Case Managers shall hire or promote staff on or after the date these regulations become effective that meet the following criteria:~~

~~16.2.6.1.1A bachelor's degree from an accredited college or university in chemical dependency, psychology, social work, counseling, or nursing and five (5) years of documented clinical experience working in the field of mental health and/or addictions counseling.~~

~~16.2.6.2 Qualifications for the position of Assistant Clinician:~~

~~16.2.6.2.1 Each individual hired or promoted to the position of Assistant Clinician on or after the date these regulations become effective shall meet the following criteria:~~

~~16.2.6.2.1.1A bachelor's degree from an accredited college or university in psychology, social work, counseling or nurse with less than five (5) years of documented clinical experience working in the field of mental health counseling; OR~~

~~16.2.6.2.1.2 The individual is a student enrolled in a course of study while completing a practicum or internship.~~

~~16.2.7 Programs may employ staff that dually meets the staffing requirements in §6.0 and §16.1 of these standards with the exception of §16.1.3: Clinical supervisor.~~

~~16.3 Staff Training~~

~~16.3.1 In addition to staff training and development in §5.1.7 of these standards, co-occurring treatment programs shall include:~~

~~16.3.1.1 At orientation:~~

~~16.3.1.1.1 Training in the relationship between substance use disorders and mental health disorders;~~

~~16.3.1.1.2 Training in the use of medication with co-occurring disorder clients including the use of buprenorphine, and other Opioid antagonist medications; and~~

~~16.3.1.1.3 Training in DSM five (5) Axis Diagnosis.~~

~~16.3.1.2 Annually thereafter:~~

~~16.3.1.2.1 Ten (10) hours of training specific to the treatment of clients with co-occurring mental health and substance use disorders.~~

~~16.3.1.2.2 Ongoing training specific to co-occurring disorder treatment as part of the staff member's individualized training plan required in §5.1.7.2 of these standards.~~

~~16.4 Clinical Supervision~~

~~16.4.1 Staff who meet the criteria for Assistant Clinician in §16.1.6.2 of these standards shall receive clinical supervision in accordance with §6.1.5.2 and §6.1.5.3 of these standards.~~

~~16.5 Services~~

~~16.5.1 Qualified Psychiatric Practitioner~~

~~16.5.1.1 Qualified Psychiatric Practitioners shall be available to staff at all times.~~

~~16.5.1.2 Qualified Psychiatric Practitioners shall conduct a psychiatric evaluation within thirty (30) days of admission to the co-occurring treatment program to include:~~

~~16.5.1.2.1 Psychiatric history;~~

~~16.5.1.2.2 Medication history;~~

~~16.5.1.2.3 Mental Status; AND~~

~~16.5.1.2.4 DSM five (5) Axis Diagnosis.~~

~~16.5.1.3 Qualified Psychiatric Practitioners shall meet with consumers for regularly scheduled appointments at intervals determined to be most beneficial for the consumer, but no less than every six months.~~

~~16.5.2 Medication monitoring~~

~~16.5.2.1A Qualified Psychiatric Practitioner will explain to the consumer the rationale for each medication prescribed as well as the medication's risks/benefits.~~

- 16.5.2.1.1 Informed consent shall be obtained for each medication prescribed at the time it is prescribed.
- 16.5.2.1.2 Informed consent shall be updated, at a minimum, annually in concert with the annual psychiatric evaluation.
- 16.5.2.2 Rationale for all changes in medication orders shall be documented in the Qualified Psychiatric Practitioner's notes.
- 16.5.2.3 All medication orders in the consumer's case record shall include:
 - 16.5.2.3.1 Name of the medication;
 - 16.5.2.3.2 Dosage;
 - 16.5.2.3.3 Route of administration;
 - 16.5.2.3.4 Frequency of administration;
 - 16.5.2.3.5 Signature of the Qualified Psychiatric Practitioner prescribing the medication; and
 - 16.5.2.3.6 All known allergies.
- 16.5.2.4 Medication orders shall be documented on a medication order form and include:
 - 16.5.2.4.1 Date of initiation;
 - 16.5.2.4.2 Date of discontinuance;
 - 16.5.2.4.3 Name of medication;
 - 16.5.2.4.4 Route of administration;
 - 16.5.2.4.5 Frequency of administration; AND
 - 16.5.2.4.6 Signature of the person documenting the orders.
- 16.5.2.5 All medication orders shall be reviewed at each face-to-face meeting with the consumer and the review shall be reflected in the progress notes written by a Qualified Psychiatric Practitioner at the time of the consumer's visit.
- 16.5.3 A Qualified Psychiatric Practitioner's progress note shall be completed after each meeting with a consumer and include but not be limited to:
 - 16.5.3.1 The consumer's report of progress;
 - 16.5.3.2 The content of the meeting;
 - 16.5.3.3 The Qualified Psychiatric Practitioner opinion of the consumer's status;
 - 16.5.3.4 Current DSM five (5) Axis Diagnosis; AND
 - 16.5.3.5 Continuation of the plan of treatment in conjunction with the consumer's treatment plan.
- 16.5.4 Annual review by Qualified Psychiatric Practitioner
 - 16.5.4.1 Qualified Psychiatric Practitioner shall review each consumer's record annually and provide documentation of:
 - 16.5.4.1.1 A clinical review of the consumer's progress over the year;
 - 16.5.4.1.2 Any changes noted;
 - 16.5.4.1.3 Mental status exam;
 - 16.5.4.1.4 Observations;
 - 16.5.4.1.5 Impressions;
 - 16.5.4.1.6 DSM five (5) Axis Diagnosis; AND
 - 16.5.4.1.7 Plan.
- 16.5.5 Staff shall monitor and document consumer tolerance, compliance in following prescribed medication treatment and medication side effects to include the following:
 - 16.5.5.1 Laboratory studies for all medications which require laboratory monitoring as recommended in the most current Physician's Desk Reference.
 - 16.5.5.1.1 Laboratory studies shall be reviewed and signed by a Qualified Psychiatric Practitioner or RN within two (2) days of receipt.
 - 16.5.5.1.2 Results of laboratory studies shall be documented in the consumer's chart within thirty (30) days.
 - 16.5.5.2 AIMS (Abnormal Involuntary Movement Scale) shall be performed no less than annually for consumers whose medication includes Tardive Dyskinesia as possible side effects of the medication.
 - 16.5.5.3 Monitoring of vital signs at each visit with a Qualified Psychiatric Practitioner shall include:
 - 16.5.5.3.1 Temperature;
 - 16.5.5.3.2 Blood pressure;
 - 16.5.5.3.3 Pulse; and

~~16.5.5.3.4 Respiration.~~

~~16.5.6 Screening and Assessment~~

~~16.5.6.1 Co-Occurring treatment programs will utilize a screening tool approved by DSAMH to screen all consumers for substance use disorders and mental health symptoms at intake, and annually thereafter.~~

~~16.5.6.2 Based on the screening results:~~

~~16.5.6.2.1 Assessment will be conducted using tools approved by DSAMH; AND~~

~~16.5.6.2.2 Clients will be placed in appropriate levels of care to meet their substance use and mental health needs.~~

~~16.5.7 Case Management~~

~~16.5.7.1 Based on the needs of the client, case management coordination shall include:~~

~~16.5.7.1.1 Coordination of medical services with the consumer's primary care physician when needed;~~

~~16.5.7.1.2 Linkage to medical services when a primary care physician has not been identified;~~

~~16.5.7.1.3 Coordination of crisis intervention and stabilization services as appropriate;~~

~~16.5.7.1.4 Assistance with achieving goals for independence as defined by the consumer;~~

~~16.5.7.1.5 Linkage to resources and opportunities through:~~

~~16.5.7.1.5.1 Support groups including but not limited to:~~

~~16.5.7.1.5.1.1 Sober support groups that meet the needs of co-occurring consumers;~~

~~16.5.7.1.5.1.2 Peer support/peer mentoring networks;~~

~~16.5.7.1.5.1.3 Social support networks;~~

~~16.5.7.1.5.1.4 Social skills training networks;~~

~~16.5.7.1.5.1.5 Family support networks; and~~

~~16.5.7.1.5.1.6 Other community services as needed.~~

~~16.5.7.1.6 Safe/decent/affordable housing when needed;~~

~~16.5.7.1.7 Entitlements;~~

~~16.5.7.1.8 Education and vocational services;~~

~~16.5.7.1.9 Transportation to and from the program; and~~

~~16.5.7.1.10 Other activities carried out in collaboration with the consumer.~~

~~16.5.7.2. When a Case Manager meeting the criteria of §16.2.6 of these standards is the sole provider of case management services, case loads shall not exceed a one to forty (1:40) staff: consumer ratio.~~

~~16.5.8 Psycho-Education and Counseling~~

~~16.5.8.1 Programs shall provide psycho-education for all consumers and family members on:~~

~~16.5.8.1.1 The efficacy of medications used for mental health diagnosis and the effects of substances on these medications; and~~

~~16.5.8.1.2 The treatment and maintenance of co-occurring disorders.~~

~~16.5.8.2 When appropriate, programs shall provide counseling that includes:~~

~~16.5.8.2.1 Group therapy that will support maintenance and stability of the consumer's psychiatric and substance use disorder;~~

~~16.5.8.2.2 Individual therapy to address all therapeutic issues that will support maintenance and stability of the consumer's psychiatric and substance use disorder; and~~

~~16.5.8.2.3 Family therapy to address therapeutic issues within the family that will support maintenance and stability of a consumer's psychiatric and substance use disorder.~~

~~16.5.8.3 Co-occurring treatment programs shall offer ample opportunity to consumers to attend community support groups that will enhance treatment for both mental health diagnosis and substance use disorders. Groups shall include but not be limited to:~~

~~16.5.8.3.1 In-house support groups provided by the co-occurring treatment program; and/or~~

~~16.5.8.3.2 Linkage to 12 step groups that support dual recovery for mental health diagnosis and substance use disorders (e.g. "Double Trouble"); and/or~~

~~16.5.8.3.3 Linkage to faith-based or other community networks including education programs, physical fitness programs, etc... that support dual recovery for mental health diagnosis and substance use disorders.~~

Part IV: Deemed Status

17.0 Joint Commission on the Accreditation of Healthcare Organizations (JCAHO)

17.1 Deemed Status Categories:

17.1.1 Programs with Full Accreditation may qualify for a 2 year license.

17.1.2 Programs that are accredited as part of a merger, consolidation or acquisition must submit verification that JCAHO will extend accreditation to the new entity.

17.2 Notification of Audit:

17.2.1 Programs must inform DSAMH of all JCAHO visits whether announced or unannounced. The Quality Assurance Unit shall be notified in writing of a scheduled visit no less than 30 days prior to the visit. The Quality Assurance Unit shall be notified by phone or email of an unannounced visit within twenty four (24) hours of the first day of the visit.

17.3 Reporting to DSAMH

17.3.1 Programs must notify DSAMH of any immediate threat to life that is discovered by JCAHO during the visit within 24 hours of the day that the threat to life is discovered.

17.3.2 Programs must report all *sentinel events* to DSAMH within twenty four (24) hours accompanied by the root cause analysis, action plan and action plan follow up activity reports prepared according to JCAHO guidelines.

17.3.3 Programs must submit to DSAMH any corrective action to address *sentinel events* at the same time they are submitted to JCAHO.

17.3.4 Programs must submit to DSAMH any other correspondence required by JCAHO during the course of the Accreditation period and/or between each JCAHO review.

17.4 Deemed Status Revocation

17.4.1 DSAMH can revoke Deemed Status standing at any time, but specifically when:

17.4.1.1 A program is unsuccessful in receiving Accreditation, or Provisional Accreditation from JCAHO;

17.4.1.2 In response to a sentinel event;

17.4.1.3 When reporting to DSAMH does not occur in according with the time table established above;

17.4.1.4 Following a survey by DSMAH when it is determined that the program is not operating under the JCAHO guidelines and/or DSAMH licensure standards.

17.4.2 Once revoked, a program must wait one (1) year before reapplying for Deemed Status. DSAMH must conduct a site review before restoring Deemed Status.

17.5 Program Exemptions:

17.5.1 Programs are exempt from the Division of Substance Abuse and Mental Health standards for Substance Abuse Treatment Programs with the exception of:

17.5.1.1 Standards Applicable to all Programs:

17.5.1.1.1 Section §5.0:

17.5.1.1.1.1 Subsection §5.1.2.1;

17.5.1.1.1.2 Subsection §5.1.4;

17.5.1.1.1.3 Subsection §5.1.7.1;

17.5.1.1.1.4 Subsection §5.1.7.2;

17.5.1.1.1.5 Subsection §5.1.7.3;

17.5.1.1.1.6 Subsection §5.1.8;

17.5.1.2 Section §6.0: Programs must be in compliance with all of section §6.0.

17.5.1.3 Section §8.0: Programs with Deemed Status are exempt from sub-section §8.1.2 of section §8.0. When client records are reviewed, DSAMH will accept documents in section §8.1.2. In the format accepted by JCAHO. Programs must be in compliance with all other subsections of section §8.0.

17.5.2 Section §9.0: Programs with Deemed Status are exempt from all standards in section §9.0 with the exception of §9.1.5. "smoke free facility".

17.6 Standards Applicable to Specific Settings and Modalities

17.6.1 Programs must be in compliance with all standards specific to the modality for which the program is being licensed.

12 DE Reg. 464 (10/01/08)

14 DE Reg. 471 (11/01/10)

18.0 Commission on Accreditation of Rehabilitation Facilities (CARF)

18.1 Deemed Status Categories

18.1.1 Programs with Three-Year Accreditation may qualify for a two (2) year license.

18.1.2 Programs that are accredited as part of a merger, consolidation or acquisition must submit verification that CARF will extend accreditation to the new entity.

18.2 Notification of Audit:

18.2.1 Programs must inform DSAMH of all CARF visits whether announced or unannounced. The Quality Assurance Unit should be notified in writing of a scheduled visit no less than 30 days prior to the visit. The Quality Assurance Unit should be notified by phone or email of an unannounced visit within 24 hours of the first day of the visit.

18.3 Reporting to DSAMH

18.3.1 Programs must notify DSAMH of any immediate threat to life that is discovered by CARF during the visit within twenty-four (24) hours of the day the threat to life is discovered.

18.3.2 Programs must report all other significant events to DSAMH within twenty-four (24) hours accompanied by the investigation report; action plan and action plan follow up activity reports prepared according to CARF guidelines.

18.3.3 Programs must submit to DSAMH any corrective action to address significant events at the same time they are submitted to CARF.

18.3.4 Programs must submit to DSAMH any other correspondence required by CARF during the course of the Accreditation period and/or between each CARF review.

18.4 Deemed Status Revocation

18.4.1 DSAMH can revoke Deemed Status standing at any time, but specifically when:

18.4.1.1 A program is unsuccessful in receiving Three-Year, or One-Year, Accreditation from CARF;

18.4.1.2 In response to a significant event;

18.4.1.3 When reporting to DSAMH does not occur in accordance with the time table established above;

18.4.1.4 Following a survey by DSAMH when it is determined that the program is not operating under the CARF guidelines and/or DSAMH licensure standards.

18.4.2 Once revoked, a program must wait 1 year before reapplying for Deemed Status. DSAMH must conduct a site review before restoring Deemed Status.

18.5 Program Exemptions:

18.5.1 Programs are exempt from the Division of Substance Abuse and Mental Health standards for Substance Abuse Treatment Programs with the exception of:

18.5.1.1 Standards Applicable to all Programs:

18.5.1.1.1 Section §5.0: Programs with Deemed status must be in compliance with the following subsections of section §5.0:

18.5.1.1.1.1 Subsection §5.1.3.1;

18.5.1.1.1.2 Subsections § 5.1.6.3.5.3., §5.1.6.3.5.5., §5.1.6.3.5.6., §5.1.6.3.5.7., §5.1.6.3.5.8., §5.1.6.3.5.9;

18.5.1.1.1.3 Subsection §5.1.6.4;

18.5.1.1.1.4 Subsection §5.1.6.5;

18.5.1.1.1.5 Subsection §5.1.7.4.

18.5.1.1.2 Section §6.0: Programs must be in compliance with all of section §6.0.

18.5.1.1.3 Section §8.0: Programs with Deemed Status are exempt from sub-section §8.1.2 of section §8.0. When client records are reviewed, DSAMH will accept documents in section §8.1.2 in the format accepted by CARF. Programs must be in compliance with all other subsections of section §8.0.

18.5.1.1.4 Section §9.0: Programs must be in compliance with standard §9.1.5: "smoke free facility".

18.5.1.2 Standards Applicable to Specific Settings and Modalities

18.5.1.2.1 Programs must be in compliance with all standards specific to the modality for which the program is being licensed.

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19.0 Council on Accreditation (COA)

19.1 Deemed Status Categories

- 19.1.1 Programs with Three Year or Four Year Accreditation may qualify for a 2 year license.
- 19.1.2 Programs that are accredited as part of a merger, consolidation or acquisition must submit verification that COA will extend accreditation to the new entity.
- 19.2 Notification of Audit:
 - 19.2.1 Programs must inform DSAMH of all COA visits whether announced or unannounced. The Quality Assurance Unit should be notified in writing of a scheduled visit no less than 30 days prior to the visit. The Quality Assurance Unit should be notified by phone or email of an unannounced visit within 24 hours of the first day of the visit.
- 19.3 Reporting to DSAMH
 - 19.3.1 Programs must notify DSAMH of any immediate threat to life that is discovered by COA during the visit within 24 hours of the day the threat to life is discovered.
 - 19.3.2 Programs must report all other hazardous or emergency situations to DSAMH within 24 hours accompanied by the investigation report; action plan and action plan follow up activity reports prepared according to COA guidelines.
 - 19.3.3 Programs must submit to DSAMH any corrective action to address hazardous or emergency situations at the same time they are submitted to COA.
 - 19.3.4 Programs must submit to DSAMH any other correspondence required by COA during the course of the Accreditation period and/or between each COA review.
- 19.4 Deemed Status Revocation-
 - 19.4.1 DSMAH can revoke Deemed Status standing at any time, but specifically when:
 - 19.4.1.1 A program is unsuccessful in receiving Three Year or Four Year Accreditation from COA;
 - 19.4.1.2 In response to a hazardous or emergency event;
 - 19.4.1.3 When reporting to DSAMH does not occur in accordance with the time table established above;
 - 19.4.1.4 Following a survey by DSMAH when it is determined that the program is not operating under the COA guidelines and/or DSAMH licensure standards.
 - 19.4.2 Once revoked, a program must wait 1 year before reapplying for Deemed Status. DSAMH must conduct a full site review before restoring Deemed Status.
- 19.5 Program Exemptions:
 - 19.5.1 Programs are exempt from the Division of Substance Abuse and Mental Health standards for Substance Abuse Treatment Programs with the exception of:
 - 19.5.1.1 Standards Applicable to all Programs:
 - 19.5.1.1.1 Section §5.0: Programs with Deemed status must be in compliance with the following subsections of section 5.0:
 - 19.5.1.1.1.1 Subsection §5.1.3.1;
 - 19.5.1.1.1.2 Subsections §5.1.6.3.5.3, §5.1.6.3.5.5, §5.1.6.3.5.6, §5.1.6.3.5.7, §5.1.6.3.5.8, §5.1.6.3.5.9;
 - 19.5.1.1.1.3 Subsection §5.1.6.4;
 - 19.5.1.1.1.4 Subsection §5.1.6.5;
 - 19.5.1.1.1.5 Subsection §5.1.7.4.
 - 19.5.1.1.2 Section §6.0: Programs must be in compliance with all of section §6.0.
 - 19.5.1.1.3 Section §8.0: Programs with Deemed Status are exempt from sub-section 8.1.2.1.1 of section 8.0. When client records are reviewed, DSAMH will accept documents in section 8.1.2 in the format accepted by COA. Programs must be in compliance with all other subsections of section §8.0.
 - 19.5.1.1.4 Section §9.0: Programs must be in compliance with standard §9.1.5: "smoke free facility".
 - 19.5.1.2 Standards Applicable to Specific Settings and Modalities
 - 19.5.1.2.1 Programs must be in compliance with all standards specific to the modality for which the program is being licensed.

Part I: General Provisions

1.0 Purpose

The Department is issuing these regulations to promote the health and well-being of clients receiving services in substance use treatment programs and facilities including those that treat, mental health and co-occurring disorders.

located within the state of Delaware. They are not intended to limit additional contract requirements for such programs and facilities with which a service provider may be expected to comply.

2.0 Statutory Authority and Applicability

- 2.1 The Department is authorized by 16 Del.C. Chs. 1 and 22 to license and regulate substance use treatment programs and facilities. **These regulations shall apply to any program or facility** as defined in 16 Del.C. Ch. 22 and address the minimum acceptable standards and programmatic conditions for clients receiving services in substance use treatment or rehabilitation service or program in Delaware. No organization or entity shall manage or operate such a treatment program or facility within the state of Delaware unless it has been so licensed by the Department.
- 2.2 These regulations shall apply to all non-profit, for-profit, and State-operated, clinics, facilities, and programs that provide substance use treatment services to individuals in Delaware. When established, these regulations shall also apply to both health homes (including care facilities that serve clients with behavioral health needs) and behavioral health homes – that are approved under the State Medicaid Plan.

3.0 Definitions

“**42 CFR Part 2**” means part 2 of Title 42 of the U.S. Code of Federal Regulations referring to the confidentiality of substance abuse client records, as the same may be amended.

“**Admission**” means the point in a client’s relationship with a program when the intake process has been completed and the program begins to provide services.

“**Agency**” means any partnership, corporation, association, or other legal entity, except for an individual practitioner and group practices, that provides, is seeking to provide, or holds itself out as providing substance use treatment and/or rehabilitation services or program(s). An agency may operate more than one program or service.

“**Applicant**” means any agency that has submitted a written application for a license to operate a substance use, non-substance-related addictive disorder, mental health, or co-occurring disorder treatment or rehabilitation service or program in Delaware.

“**ASAM**” means the American Society of Addiction Medicine.

“**ASAM Criteria**” means the latest version of the American Society of Addiction Medicine (ASAM) Criteria.

“**Behavioral Health**” refers in these regulations to any substance use, addictive, and/or mental health disorder.

“**Behavioral Health Technician**” means an unlicensed individual, who is at least 18 years of age with a high school diploma or equivalent who has been trained in the relevant ASAM Level of Care criteria.

“**Behavioral Management**” means any intervention or treatment that utilizes positive reinforcement and/or restrictions to help a client receiving services to develop and/or strengthen recovery-oriented behaviors and to address and correct treatment targeted behaviors

“**Client Record**” means the comprehensive file for each agency client containing all the information required by Section 8.0 of these regulations and maintained by the agency providing services to the client pursuant to these regulations. Records must be available on-site or electronically accessible at all times.

“**Clinical Director**” means an individual who, by virtue of education, training, and experience, satisfies the requirements of these regulations and is authorized by the agency administrator to provide clinical oversight of the treatment program. The clinical director may also serve as clinical supervisor when directed to do so by the agency’s governing body.

“**Clinical Supervisor**” means an individual who, by virtue of education, training, and experience, satisfies the requirements of these regulations; and is authorized by the agency to provide clinical supervision for all clinical staff.

“**Compliance**” means a program adheres to these regulations in accordance with the relevant licensing standards.

“**Continuing Care**” means those services recommended by the program to the client upon discharge from a program that support and increase the gains made during the client’s treatment.

“**Co-occurring Disorder**” means substance use, addictive disorders, and mental health disorders that co-exist; a term interchangeable with “dual diagnosis”.

“**Counseling**” means the process in which a Counselor works with a client, family, significant other, or a group of clients, families or significant others, to assist them to understand issues, consider alternatives, and change behaviors.

- : Individual counseling is the face-to-face, video or telephone interaction between a Counselor and an individual client for a specific therapeutic purpose.

- Family counseling is the face-to-face interaction between a Counselor and the family member(s)/ significant other(s) of a client for a specific therapeutic purpose.
- Group counseling is the face-to-face interaction between a Counselor and two or more clients or clients' families/significant others for a specific therapeutic purpose.

“Day” means, unless otherwise specified, one (1) calendar day.

“Deemed Status” means a licensure status given to a program which is accredited by the Joint Commission (JC) Commission on Accreditation of Rehabilitation Facilities (CARF), or the Council on Accreditation (COA) and which exempts the program from Division monitoring pursuant to these regulations except for complaint based investigations and corresponding actions by the Division.

“Department of Health and Social Services” means the State of Delaware Department of Health and Social Services, including its Division of Substance Abuse and Mental Health (“DSAMH” or “Division”).

“Discharge” means the point at which a client’s active involvement with a program is terminated.

“Division Director” means the Director of DSAMH or the Director’s designee.

“Evidence-based programs and practices (EBPs)” means programs or practices that are validated by some form of documented scientific evidence (in contrast to approaches that are based on tradition, convention, belief, or anecdotal evidence). A listing of applicable EBPs can be found at: <http://www.nrepp.samhsa.gov/>.

“Facility” means the physical area, grounds, building or portions thereof, where the program is operated, including administrative offices.

“Follow-up” means the process for determining the status of an individual who has been referred to an outside resource for assistance or services, including an individual who has been discharged from services, OR the process for determining an agency’s compliance with these standards after an agency audit has been completed.

“HIPAA” means the Health Insurance Portability and Accountability Act of 1996, 45 CFR Parts 160 and 164.

“History and Physical” means the initial clinical evaluation and examination of a client to include a medical history, a nursing assessment, a physical examination, and if needed, laboratory tests, tests for contagious diseases, and other related diagnostic tests.

“Inactive Status” means a program is not eligible to see clients; however is provided with a provisional license.

“Initial Recovery Plan” means a preliminary recovery plan developed upon admission to the program. The initial recovery plan is a working document created with input from the client and multi-disciplinary program staff.

“Intake” means the gathering of personally identifying and clinical data required to determine whether a client should be admitted to a program.

“Licensed Behavioral Health Practitioner (LBHP)” means a professional who is licensed in the State of Delaware to diagnose and treat mental illness or substance abuse acting within the scope of all applicable State laws and their professional license. Qualifying LBHP recognized for the purpose of these regulations are as follows:

- Licensed Psychologists;
- Licensed Clinical Social Workers (LCSWs);
- Licensed Professional Counselors of Mental Health (LPCMHS);
- Licensed Marriage and Family Therapists (LMFTs);and
- Licensed Chemical Dependency Professional (LCDP)

“Medical Director” means a medical doctor authorized by an agency’s governing body and policies to be responsible for overseeing medical services provided in a licensed program.

“Medically Supervised Withdrawal” means dispensing of medically appropriate medications in gradually decreasing doses to alleviate adverse physical or psychological effects incident to withdrawal from the continuous or sustained use of opioid drugs. The purpose of medically supervised withdrawal is to bring a patient maintained on maintenance medication to a medication-free state within a target period.

“Medication Assisted Treatment (MAT)” means the use of medications, in combination with counseling and behavioral therapies, to provide a whole-patient approach to the treatment of substance use disorders.

“Non-Substance-Related Addictive Disorder” means behavioral addictions, such as gambling, that are similar to substance-related disorders in clinical expression, brain origin, comorbidity, physiology, and treatment and result in preoccupation that can lead to clinically significant impairment or distress.

“Opioid Treatment Program (OTP)” means a program that is federally certified by Substance Abuse and Mental Health Services Administration (SAMHSA) under 42 CFR Part 8.11 to provide specific medication-assisted treatment to opioid-dependent persons, as regulated by DSAMH under the purview of the Delaware State Opioid Treatment Authority (SOTA).

“Program” means the substance use treatment modalities of service provided by an agency.

“Program Director” means an employee responsible to the agency for the direct operation of a program.

“Program Physician” means a physician either employed by, or under written contract with, an agency for the purpose of providing direct services to clients served by the agency.

“Progress Notes” means written or electronic record of services and supports provided to an individual documenting the individual's participation in, and response to, treatment, progress in recovery, and progress toward intended outcomes.

“Provisional license” means the document issued by the Division that authorizes a program to provide substance use, non-substance-related addictive disorder, and/or co-occurring disorder treatment or rehabilitation for up to one hundred and eighty (180) days when first time applicant for licensure has had its application accepted by the Division pending a full licensure inspection or a current licensee has been determined by the Division to be not in compliance with these regulations pending additional action.

“Psychiatrist” means an individual who possesses a valid State of Delaware license to practice medicine and has completed an accredited residency training program in psychiatry.

“Qualified Health Professional (QHP)” means a practitioner who is currently registered with their respective Delaware professional board and provides clinical and administrative oversight and supervision of non-credentialed staff in a manner consistent with their scope of practice specifically for behavioral health services. QHPs include LCSWs, LPCMHs, LMFTs, LCDPs, and Psychologists.

“Qualified Medical Professional (QMP)” means Advanced Practice Registered Nurse (APRN), Physicians Assistants (PA), Nurse Practitioner (NP), Doctor of Medicine (MD), and Doctor of Osteopathic Medicine (DO).

“Quality Assurance” means the process of objectively and systematically monitoring, and evaluating the quality and effectiveness of client care outcomes and to avoid, identify and/or resolve client care quality issues

“Recovery” means a process of change through which individuals improve their health and wellness, live a self-directed life, and strive to reach their full potential.

“Recovery plan update” is a process completed according to the treatment modality for which the program is licensed. In this process the clinical supervisor and counselor review prior recovery plans, and, in collaboration with the client, family/natural supports, and other relevant providers, establish current goals and objectives based on the client's progress and/or changing needs.

“Safety Plan” means a practical guide that is personalized to the client that identifies specific triggers/stressors, warning signs/symptoms, coping skills, relapse prevention, supports, etc.

“Secretary” means the Cabinet Secretary of the Delaware Department of Health and Human Services.

“Signature/signed” means, at a minimum, the writers' first name, last name, title or credentials and date or an authentic digital signature or the client or legal guardian's first and last name and date when required.

“Substance” means alcohol, nicotine, other drugs and medications or compounds or materials having chemical properties that after entering a human body, affects the person in a manner that alters mood and/or perception.

“Substance Use Disorder” - the essential feature of a substance use disorder is a cluster of cognitive, behavioral and physiologic symptoms indicating that the individual continues using the substance despite significant substance-related problems.

“Treatment” means the process a client undergoes to understand his or her alcohol or drug use and/or mental health diagnosis and choices made to change his or her behavior and improve health and functioning.

“Unlicensed counselors and assessors” includes, Bachelor and Master level clinicians, certified alcohol and drug counselor (CADC), internationally certified alcohol and drug counselor (ICADC), certified co-occurring disorders professional (CCDP), internationally certified co-occurring disorders professional (ICCDP), internationally certified co-occurring disorders professional diplomat (ICCDPD).

“Withdrawal management” means a set of interventions aimed at managing acute intoxication and withdrawal. It is often the first step taken by clients with a substance use disorder and typically needs to be followed by referral to a continuum of health and social services that is inclusive of assessment services, active treatment and continuing care.

4.0 Licensing Requirements and Procedures

4.1 General Provisions

- 4.1.1 **No person shall establish, conduct or maintain in this State a substance use treatment program or facility to include co-occurring treatment without first obtaining a license from the Department of Health and Social Services.**

- 4.1.2 Any agency seeking to operate a program covered under these regulations shall be licensed in accordance with these regulations for each program it seeks to operate.
- 4.1.3 Each agency's license shall list one or more categories of program that the agency is authorized to provide and the agency's location. The license shall be posted in a conspicuous place on the licensed premises.
- 4.1.4 A license is not transferable from program to program or agency to agency. An agency which operates programs licensed pursuant to this regulation which undergoes a merger, consolidation or acquisition must reapply for a license before seeing clients.
- 4.1.5 Separate licenses are required for programs maintained in separate locations, even when operated by the same agency. A separate license is required when an agency is operating in the same building and providing multiple program service categories.
- 4.1.6 The issuance of a license to a program is not a commitment by the Division or any third-party to fund the program or contract with the program for services.
- 4.1.7 By issuing a license to a program, the Division is in no way assuming any legal or financial responsibility for the program or the agency which operates the program.
- 4.1.8 In order to be granted a license, the Division must determine that a program is in compliance with all of the requirements set forth in Part II of these regulations as well as the relevant program-specific requirements in Part III of these regulations. To do this, a program must demonstrate compliance with each individual section of programmatic requirements. Compliance will not be determined based upon an overall aggregate scoring of the relevant provisions. The Division will not grant a license if the program fails to achieve compliance in Sections of Part II of these regulations or the relevant Section in Part III of these regulations.
- 4.2 Licensing Categories. Program and service categories for which licenses may be issued are:
 - 4.2.1 Ambulatory Withdrawal Management with Extended Onsite Monitoring (ASAM Level 2-WM and ASAM Level 2-WM-23 hour)
 - 4.2.2 Outpatient Substance Use Disorder Services (ASAM Level 1)
 - 4.2.3 Intensive Outpatient Treatment (ASAM Level 2.1)
 - 4.2.4 Partial Hospitalization Program (PHP) (ASAM Level 2.5) – applies to PHP such as “Day Treatment” that do not fall under a hospital accreditation.
 - 4.2.5 Opioid Treatment Services
 - 4.2.6 Clinically Managed Residential Withdrawal Management (ASAM Level 3.2-WM)
 - 4.2.7 Medically Monitored Inpatient Withdrawal Management (ASAM Level 3.7-WM)
 - 4.2.8 Clinically Managed Low Intensity Residential Treatment (ASAM Level 3.1)
 - 4.2.9 Clinically Managed Population-Specific High Intensity Residential Treatment (ASAM Level 3.3)
 - 4.2.10 Clinically Managed High Intensity Residential Treatment (ASAM Level 3.5)
 - 4.2.11 Medically Monitored Intensive Inpatient Treatment (ASAM Level 3.7)
- 4.3 Application Procedures and Processes
 - 4.3.1 All persons or entities applying for a license shall submit an application for licensure to the Department and payment of the required fee.
 - 4.3.2 All agencies applying for a license for the first time or for any new programs shall meet with DSAMH Quality Assurance staff for the purpose of receiving technical assistance regarding the licensure criteria and procedures.
 - 4.3.3 A separate application shall be completed for each program at each location at which an agency intends to operate a substance use, non-substance-related addictive disorder, or co-occurring disorder treatment or rehabilitation service or program.
 - 4.3.4 The applicant may withdraw the application at any time by notifying the Division in writing.
 - 4.3.5 Applicants shall submit to the Department the following information on forms provided by the Division:
 - 4.3.5.1 A description of the services to be provided by the program, including a statement of the program philosophy, goals and objectives, and a description of the methodology for each service element
 - 4.3.5.2 Policy and procedure manuals and any other information relevant information requested by the Department, including copy of the program's complete proposed policies and procedures manual if the application is for initial licensure.
 - 4.3.5.3 Disclosure of information in accordance with U.S. Health and Human Services Office of Inspector General (OIG) under 42 U.S.C. §1320a-7.
 - 4.3.5.4 The Department has the authority to modify, update, or change the application forms at any time and without notice to current, pending, or future licensees.

- 4.3.6 The Division shall determine whether an application is complete and shall notify the applicant in writing if additional information is required to complete the application.
- 4.3.7 After an applicant submits a completed application, including any additional documentation requested by the Department and the Department reviews the completed application and determines it to be satisfactory; the Department shall grant the applicant a Provisional License.
- 4.3.8 Before the expiration of the Provisional License, the Division will inspect the applicant's facility and follow the process set forth in subsections 4.4 - 4.7 to confirm that the requirements set forth in Part II General Standards and Part III Specific Standards have been met.
- 4.3.9 A license is granted upon verification that the requirements set forth in these regulations have been met.
- 4.3.10 An applicant for renewal shall submit its completed application at least ninety (90) days, but not more than one hundred and twenty (120) days before its current license expires.
 - 4.3.10.1 An applicant for renewal is eligible to request deemed status pursuant to subsection 4.11.
- 4.3.11 Inactive Status
 - 4.3.11.1 A program may request to go on inactive status instead of renewing the license.
 - 4.3.11.2 Inactive status can be granted for periods of up to six months.
 - 4.3.11.3 A program in Inactive Status is considered provisionally licensed and may not engage, treat, or see clients during an inactive status.
- 4.3.12 In order to change from an Inactive Status to a full license, a program must successfully complete the license renewal process and may not see clients until the inactive status is removed.
- 4.4 Inspection and Investigation
 - 4.4.1 By applying for or accepting a license from the Department, an applicant or licensee authorizes the Division and its representatives to conduct the inspections and investigations necessary to determine compliance with applicable licensing standards.
 - 4.4.2 Unannounced inspections of any facility by authorized representatives of the Department may occur anytime upon receipt of a complaint or report of an adverse event which the Department deems to be credible.
 - 4.4.3 Inspections and investigations may include announced or unannounced on-site inspections of the program and its operation to include: review of program records, clinical records and other documents maintained by the program; and acquisition of other information, including otherwise privileged or confidential information, from any other person who may have information bearing on the applicant's or licensee's compliance or ability to comply with these regulations.
 - 4.4.4 At the conclusion of the inspection or investigation the Division shall conduct an exit interview with the agency. The exit interview may occur at the facility or other specified locations as deemed by the Division.
 - 4.4.5 Within thirty (30) days of the exit interview, the Division shall compile a Survey Summary Report citing strengths and recommendations for addressing any identified deficiencies in meeting these regulations. The Survey Summary Report shall address at a minimum, the following topics: (i) Client Records; (ii) Consents; (iii) Assessments; (iv) Recovery Planning; (v) Progress Notes; (vi) Discharge Summaries; and (vii) all applicable program specific requirements as set out in Parts III and IV.
 - 4.4.6 Within ten (10) working days after receipt of a Survey Summary Report, the program shall submit a Corrective Action Plan (CAP) to the Division, addressing all deficiencies and areas where recommendations were made, unless otherwise directed by the Division.
 - 4.4.6.1 The CAP shall include a description of the corrective measures the program will take to address the deficiency cited in the Survey Summary Report, a target date for implementation of each corrective measure, and a description of the preventive measures implemented to ensure compliance with these regulations.
 - 4.4.6.2 The Division may perform follow-up unannounced on-site inspections to review the implementation of the CAP(s).
 - 4.4.6.3 The Division shall notify the agency in writing within one week (1) weeks of receipt of a Corrective Action Plan (CAP) whether the CAP is acceptable.
- 4.5 Licensure Action
 - 4.5.1 On the basis of the information supplied by a new or renewal applicant and any other information acquired during its investigation and inspection, including review of a program's CAP(s), the Division may take one of the following actions:
 - 4.5.1.1 Issue or renew a full license for a period of up to one (1) year when the Division determines a program is in compliance with these regulations; or

- 4.5.1.2 Issue or renew a full license for a period of up to three (3) years when the Division has granted the program deemed status and the program is in compliance with these regulations.
- 4.5.1.3 Issue a provisional license for up to one hundred and eighty (180) days when the program is not in compliance with these regulations and the applicant's failure to meet the requirements of these regulations does not jeopardize the health, safety and well-being of clients.
 - 4.5.1.3.1 A provisional license may be renewed twice by the Division for a period not to exceed ninety (90) days for each subsequent provisional license, for a maximum of one-hundred and-eighty (180) days.
 - 4.5.1.3.2 If the Division grants two sequential provisional licenses to a program, upon the granting of the second provisional license to the program, the Division may require the program to provide to the Division a transition plan for the clients served by the program outlining how the clients will be transitioned to another program should the program fail to meet the licensure standards at the conclusion of the second provisional license. If the program does fail to meet licensure standards by the conclusion of the second provisional license, the transition plan which the program previously submitted to the Division shall be implemented.
- 4.5.2 Revoke, suspend or deny a license in accordance with these regulations. A decision to revoke, suspend or deny a license in accordance with these regulations shall be communicated to the program in writing a minimum of thirty (30) days prior to the effective date of the revocation. Such notification shall include the reasons why the license was revoked, suspended, or denied and notice to the program of its right to request an administrative hearing, pursuant to subsection 4.9 of these Regulations.
- 4.5.3 The Division shall notify the program in writing by mail and email of its decision to issue or renew a license pursuant to these regulations.
- 4.6 Denial, suspension or revocation of license. A license may be denied, suspended or revoked for one or more of the following reasons:
 - 4.6.1 When a program submits false information to the Division for licensing purposes;
 - 4.6.2 When a program fails to cooperate with the Division in connection with a licensing inspection or investigation;
 - 4.6.3 When a program has deviated from the category of service listed on its license;
 - 4.6.4 When an applicant or program fails to be in compliance with the requirements of these regulations for the types of services for which application was made or for which the program was licensed, as outlined in subsection 4.1.
 - 4.6.5 When an applicant or program fails to implement the corrective action plan it submitted pursuant to subsection 4.7, unless the Division approves an extension or modification of the corrective action plan;
 - 4.6.6 When a program has violated any part of 16 Del.C., Chapter 22 or these regulations;
 - 4.6.7 When a program has a history of, or currently demonstrates, financial insolvency, such as filing for bankruptcy; being subjected to foreclosure, eviction for failure to pay rent, or termination of utility services for failure to pay bills; or failing to pay such taxes as employment or social security in a timely manner.
 - 4.6.8 When the program is in violation of a safety or sanitation law or regulation and fails to correct the violation;
 - 4.6.9 When the program, its governing body or owner participates in, condones or is associated with fraud, deceit, coercion, misrepresentation or any other illegal act;
 - 4.6.10 When the program or any of its personnel or governing body violates professional ethics;
 - 4.6.11 When the program, or any of its personnel or governing body, permits, aids or abets the commission of an unlawful act within its facilities or permits, aids or abets the commission of an unlawful act involving chemical substances within the program; or
 - 4.6.12 When the program, or any of its personnel or governing body, has participated in, condoned, associated with or knows or should have known and has permitted the continuation of any other practice that jeopardizes the safety or health or well-being of any client.
- 4.7 Procedure when a license is denied, suspended or revoked
 - 4.7.1 In accordance with 16 Del.C. §2208, when the Division determines that an applicant or licensee fails to meet minimum compliance with the requirements of these regulations for the types of services for which application was made or for which the program was licensed or has committed an act or engaged in conduct or practices justifying denial, suspension or revocation of licensure the Division shall notify the applicant or licensee by certified mail, return receipt requested, of its intent to deny, suspend or revoke the license. The "Notice of Intended Action" shall include the particular reason(s) for the proposed action and provision for a fair hearing.

- 4.7.2 Within ten (10) days after receipt of the “Notice of Intended Action,” an applicant or licensee may request a hearing by delivering a written request to the Division Director in person or by certified mail, return receipt requested. If no such request is made within ten (10) days, the Division Director shall proceed to deny, revoke or suspend said license as set forth in the notice of proposed action.
- 4.7.3 Within fifteen (15) days after receipt of an applicant’s or licensee’s request for a hearing, The Division Director shall issue a “Notice of Hearing” to the applicant or licensee and to the public. The “Notice of Hearing” shall include a statement of the time, place and nature of the hearing, a statement of the legal authority and jurisdiction under which the hearings to be held; a reference to the particular provisions of the statutes and rules involved; and a short and plain statement of the matters asserted.
- 4.7.4 All hearings conducted under this subsection shall be governed by procedures authorized by rules of the Division; the Division Director or its agent may take testimony concerning any matter within its jurisdiction and may administer oaths, summons or subpoenas for any witness and subpoenas duces tecum, which shall be served and returned as provided bylaw.
- 4.7.5 At the hearing, the applicant or licensee shall have the right to cross-examine witnesses against it, produce witnesses in its favor and to appear personally or by counsel.
- 4.7.6 All hearings shall be open to the public and a full record and transcript of the proceedings shall be prepared. The Secretary of the Department shall make a determination, which shall specify the Division’s findings of fact and conclusions. A copy of the determination shall be sent by certified mail, return receipt requested, or be personally served upon the applicant or licensee.
- 4.7.7 Copies of the transcription may be obtained by any interested party on payment of the cost of preparing such copies.
- 4.8 Renewal of License after Suspension or Revocation
- 4.8.1 A program which has had its license suspended may operate following a written determination by the Division that the reason for the suspension has been resolved. A written determination by the Division that the reason for the suspension has been resolved shall operate to terminate the suspension. A program which has filed for a hearing following a suspension, which is then later lifted upon written determination by the Division, may still proceed with the hearing, however, the hearing will be limited to the appropriateness of the initial suspension.
- 4.8.2 A program which has had its license revoked must wait one year from the date of the final determination of revocation before applying for a new license.
- 4.8.3 The suspension or revocation of a program license shall not act as a suspension or revocation of any other program licenses issued by the Division to an agency pursuant to these regulations.
- 4.8.4 The Division may consider whether an agency has previously or currently had a program license issued pursuant to these regulations suspended or revoked when determining whether to issue a new license to the agency or reinstate a suspended license.
- 4.8.5 The request for a hearing shall be in writing and shall be delivered to the Division Director in person or by certified mail, return receipt requested.
- 4.8.6 Any hearing conducted under this subsection shall not operate to stay or supersede any decision revoking or suspending a license.
- 4.8.7 Hearings under this subsection shall be conducted in accordance with 29 **Del.C.** Chapters 100 and 101 and subsection 4.7 of these regulations.
- 4.9 An Appeal when requesting licensure change of status should include the following:
- 4.9.1 Requesting a formal change to an official decision regarding program license.
- 4.9.2 When a program is found in provisional status, may be made to the DSAMH Quality Assurance Unit Director
- 4.9.3 Must be made in writing within five (5) business days after the initial license has been received.
- 4.9.4 The Director of Quality Assurance shall review the written request and issue a formal determination in writing to the licensee or applicant within ten (10) business days of the request.
- 4.9.5 Review. If the licensee or applicant fails to request an Administrative Review, a request for appeal will not be granted
- 4.9.6 If the licensee or applicant does not agree with the determination made by the Director of Quality Assurance, the licensee or applicant has the right to request a hearing in writing to the Division Director. The program will need to refer to subsection 4.7 of these regulations and follow accordingly.
- 4.10 Voluntary Program Closure

- 4.10.1 A licensee shall notify the Division in writing sixty (60) days prior to a voluntary closure of any program it is operating. The notice shall detail how the licensee will comply with these and other state and federal statutes and regulations concerning the retention and disposition of clinical records.
- 4.10.2 The licensee shall provide written notice to clients no less than thirty (30) days prior to closure, and shall make reasonable efforts to place clients in appropriate services and programs, and to ensure a responsible transition.
- 4.10.3 In the event of an emergency that requires relocation or closure of a program, the licensee shall immediately notify the Division Director and cooperate fully with the Division to facilitate transfer of clients, as necessary, and to acquire a temporary or permanent facility(ies) for relocation.

4.11 Deemed Status

- 4.11.1 The designation of deemed status shall be granted through the licensing process set forth in these regulations to programs which are accredited by a Department-approved third-party accrediting body and which meet the appropriate program-specific modalities set forth in sections 4.0 - 4.3.
- 4.11.2 Programs designated by the Division as having deemed status will be granted a license which is valid for up to three (3) years.
- 4.11.3 Program's granted deemed status will be exempt for the period of their license from Division monitoring pursuant to these regulations, except for complaint based investigations and corresponding actions by the Division
- 4.11.4 Programs granted deemed status are subject to investigations pursuant to subsection 4.4 by the Department in response to a complaints regarding client health or safety which the Department deems credible.
- 4.11.5 For the purpose of these regulations, the approved third-party accreditations recognized by the Department for the purpose of deemed status are:
 - 4.11.5.1 Full Accreditation by Joint Commission;
 - 4.11.5.2 Three (3) year accreditation by Commission on Accreditation of Rehabilitation Facilities; or
 - 4.11.5.3 Three (3) or four (4) year accreditation by Council on Accreditation.
- 4.11.6 The agency seeking deemed status for a program must submit its most recent accreditation certificate to the Department as part of its license application. Upon Department request, the agency must submit a copy of the entire accreditation report.
- 4.11.7 Deemed status is program-specific and is not transferable between programs or between agencies. An agency with one or more programs granted deemed status that undergoes a merger, consolidation or acquisition must reapply for a license, including deemed status designation, despite having deemed status prior to the merger, consolidation, or acquisition.
- 4.11.8 Any time a program granted deemed status is required to submit a plan of correction to its accrediting organization, it must submit a corresponding plan of correction to the Department.
- 4.11.9 An agency must immediately notify the Department if it's accrediting organization suspends, terminates, or revokes accreditation for a program that is licensed by the Department under these regulations. The suspension, termination, or revocation of accreditation by an accrediting body shall automatically terminate the programs deemed status and prompt an inspection and investigation of the program by the Department to ensure that it meets all licensing criteria required by a program that does not have deemed status. Upon the suspension, termination, or revocation of accreditation by an accrediting body, the Department may suspend the program's license until the program can show that it satisfies all licensing criteria required of a program that does not have deemed status.

4.12 Waiver

- 4.12.1 An application for a waiver from a requirement of these regulations shall be made in writing to the Division's Director of Quality Assurance; it shall specify the regulation from which waiver is sought, demonstrate that each requested waiver is justified by substantial hardship, and describe the alternative practice(s) proposed. The waiver request shall be posted in a prominent place in the facility and outline a process approved by the Division whereby clients can offer comments and feedback specific to the waiver request. The Division's Director of Quality Assurance Unit shall make a recommendation of action on the application to the Division Director or designee. The Division Director or designee will review the request and recommendations and make final waiver request decisions.
- 4.12.2 No waiver shall be granted if such action would result in an activity or condition that would endanger the health, safety or well-being of a client.
- 4.12.3 A waiver granted under these regulations shall be in effect for the term of the applicant's license. If a waiver is required for an additional period of time, it shall be requested as part of the licensure renewal process in accordance with subsection 4.15.

- 4.12.4 An adverse decision by the Division on a request for a waiver may be appealed in accordance with subsection 4.7.
- 4.12.5 The granting of a waiver does not constitute a permanent modification of any requirement of these regulations.
- 4.12.6 Licensees shall notify the Division within ten (10) working days when a waiver granted by the Division is no longer needed.
- 4.12.7 The Division may revoke a waiver when the alternative practice proposed in the application for waiver is determined to be ineffectual.
- 4.12.8 The Division may revoke the waiver when the program fails to implement the alternative practice as proposed in the application for waiver.

Part II: Standards Applicable to all Facilities and Programs

5.0 Staff Training and Development

- 5.1 Each agency shall establish a written staff training and development plan that shall include:
 - 5.1.2 An orientation curriculum that will ensure that all staff are familiar with the agency policies and procedures, and have a working knowledge of at least the following:
 - 5.1.2.1 Personnel policies and procedures;
 - 5.1.2.2 Agency policies and procedures regarding the reporting of cases of suspected child abuse or neglect in compliance with all applicable State and Federal statutes and regulations, including non-retaliation policies when personnel report abuse and neglect;
 - 5.1.2.3 Policies and procedures regarding clients' rights and protections;
 - 5.1.2.4 Instruction and training in the agency and facility emergency and fire plans;
 - 5.1.2.5 Policies and procedures regarding the obligation to report violations of law and applicable codes of ethics to the appropriate certification and/or licensure boards; and
- 5.2 Programs shall annually establish an individual training plan for each staff member based on the staff member's skill level, education, experience, current job functions, and job performance
- 5.3 Unlicensed and uncertified staff providing direct clinical services to clients shall complete a minimum of twenty (20) hours of training and education annually.
- 5.4 All staff, trainees and volunteers shall receive training within the first 120 days of employment in the following areas at a minimum:
 - 5.4.1 Cardio-pulmonary resuscitation (CPR);
 - 5.4.2 Basic first aid;
 - 5.4.3 Infection diseases and infection control procedures.

6.0 Staff Qualifications

- 6.1 Qualifications for the Position of Administrator
 - 6.1.1 Each agency shall have an administrator responsible for the overall management of the program and staff.
 - 6.1.2 Each administrator hired or promoted on or after the date these regulations become effective shall have at a minimum a Bachelor's Degree from an accredited college or university with at least 5 years of documented experience in human services including:
 - 6.1.2.1 At least two (2) years of experience in mental health and/or substance use disorders treatment; and
 - 6.1.2.2 A least two (2) years of relevant management experience.
- 6.2 Qualifications for the Position of Clinical Director
 - 6.2.1 Each individual, hired or promoted, to the position of Clinical Director on or after the date these regulations become effective shall have, at a minimum:
 - 6.2.1.1 A Master's Degree in counseling or a related discipline; and
 - 6.2.1.2 At least five (5) years of documented clinical experience in human services, at least three (3) years of which shall be in mental health and/or substance use disorder services; or
 - 6.2.1.3 A Licensed Behavioral Health Practitioner with at least three (3) years of documented clinical experience in mental health and/or substance use disorder services.
- 6.3 Qualifications for the Position of Clinical Supervisor

6.3.1 Each individual providing clinical supervision on or after the date these regulations become effective shall meet one of the following:

6.3.1.1 At minimum, a Bachelor's Degree from an accredited college or university with a major in chemical dependency, psychology, social work, counseling, nursing or a related field of study and full certification as a certified alcohol and drug counselor (CADC), internationally certified alcohol and drug counselor (ICADC), certified co-occurring disorders professional (CCDP), internationally certified co-occurring disorders professional (ICCDP), internationally certified co-occurring disorders professional diplomate (ICCDPD), or licensed chemical dependency professional (LCDP); or

6.3.1.2 At minimum, a Bachelor's Degree from an accredited college or university with a major in chemical dependency, psychology, social work, counseling, nursing or a related field of study and five (5) years of documented clinical experience in the substance use, mental health, or co-occurring treatment field and; or

6.3.1.3 CADCs certified prior to 2018, and who have five (5) years of documented experience but no bachelor's degree maybe considered the clinical supervisor and can supervise other CADCs; however

6.3.1.4 By January 1, 2018, all clinical supervisors will need to follow subsections 6.3.1.1 and 6.3.1.2 of these regulations when the role of clinical supervisor is identified.

7.0 Client Rights

7.1 Nondiscrimination policy

7.1.1 No agency shall deny any person equal access to its programs or facilities on the basis of race, color, religion, ancestry, sexual orientation, gender expression, national origin, or disability.

7.1.2 No agency shall deny any person equal access to its programs or facilities on the basis of age, sex, or gender except those programs that specialize in the treatment of a special population, such as, adolescents aging into adults, pregnant women, and mothers with children.

7.1.3 All agencies shall comply with 11 Del.C. §1121 (Rights of Patients in Nursing Facilities and Similar Facilities); 16 Del.C. §2220 (Substance Abuse Treatment Act Patient's Rights), and 16 Del.C. §5182 (Community Mental Health Patients' Rights), as applicable.

7.1.4 All agencies shall ensure that they comply with the federal Americans with Disabilities Act, 28 U.S.C. §§12101 et seq. and 28 Code of Federal Regulations, Part 36 (July 1991) and 16 Del.C. §2220.

7.1.5 All agencies shall ensure they comply 16 Del.C. §§2211, 2212, 2213 and 2215.

7.1.6 Programs shall provide a reasonable accommodation for clients to practice religious or spiritual belief in accordance with the program's policy and procedures.

8.0 Client Records

8.1 Maintenance of Client Records

8.1.1 Agencies shall:

8.1.1.1 Maintain a clinical record for each client receiving services that is accurate, legible, and signed (including date and time) by the staff member who provided the service

8.1.1.2 Maintain a standardized client record-keeping system that is uniform in content and format.

8.1.1.3 Establish and maintain a system that permits easy identification of and access to individual client records by authorized program staff.

8.1.1.4 Comply fully with all applicable federal and state privacy statutes and regulations, including HIPAA and 42 CFR Part 2.

8.1.1.5 Update each relevant record within twenty-four (24) hours of delivery of a service unless otherwise specified in these regulations.

8.1.2 Any agency that discontinues operations, or is merged with, or acquired by another agency is responsible for ensuring compliance with the requirements of 42 CFR §2.19, and HIPAA. The agency shall document the following in writing to the Division:

8.1.2.1 How it will adhere to 42 CFR §2.19 and HIPAA at the time it notifies the Division of the program closure in accordance with these regulations; and

8.1.2.2 How it will adhere to Section 8.0 of these regulations.

8.1.3 Agencies shall have policies and procedures that ensure compliance with all Federal and State regulations regarding storage, archiving and destruction of client records.

8.1.4 Electronic Health Records.

8.1.4.1 The use of electronic health records by the agency must comply with all applicable state and federal regulatory standards including:

8.1.4.1.1 The Health Insurance Portability and Accountability Act of 1996, P.L. 104-91 and its implementing regulations (HIPAA).

8.1.4.1.2 There shall be a plan for back-up of electronic record systems.

8.1.5 Programs shall provide a list of referral sources for the client's various needs when the agency is unable to meet the client's needs internally. The agency shall be responsible for assisting the client in enrolling in services at other agencies, and document referral efforts and outcomes in the client record.

8.1.6 Programs shall provide a minimum of twelve (12) months of records up until and including the expiration date of the current license for the purposes of licensure audit. Programs shall develop a policy that clearly outlines timelines for record retention and storage for all records beyond the required audit period.

8.2 Content of Client Records

8.2.1 A record shall be established for each client upon admission and shall include:

8.2.1.1 A Consent to Treatment form signed and dated by the client and, if the client is a minor, the client's parent or guardian, except as provided in 16 Del.C. §2210(b).

8.2.1.2 An up-to-date face sheet including the client's:

8.2.1.2.1 Date of admission;

8.2.1.2.2 Name;

8.2.1.2.3 Address;

8.2.1.2.4 Telephone number;

8.2.1.2.5 Date of birth;

8.2.1.2.6 Gender expression

8.2.1.2.7 Sex

8.2.1.2.8 The client's significant medical history documenting:

8.2.1.2.8.1 Current medical conditions;

8.2.1.2.8.2 Any medications the client is currently prescribed;

8.2.1.2.8.3 Any medications the client is currently taking;

8.2.1.2.8.4 All Allergies;

8.2.1.2.8.5 The name and telephone number of the person to contact in an emergency to include relationship;

8.2.1.3 Consent to Release Information forms

8.2.1.4 Documentation signed and dated by the client:

8.2.1.4.1 Acknowledging receipt of the notice of client rights;

8.2.1.4.2 Acknowledging his/her understanding of the agency's agreement with the confidentiality requirements of these regulations;

8.2.1.4.3 Acknowledging receipt of the program's procedures when an emergency occurs outside of the program's hours of operation.

8.2.1.5 Copies of any laboratory reports and drug tests ordered by the program;

8.2.1.6 Informed consent regarding prescribed pharmacotherapy obtained from the client prior to delivery of the medication prescription;

8.2.1.7 Results of the client's diagnostic assessment, including the client's:

8.2.1.7.1 Mental health status;

8.2.1.7.2 Psychiatric history;

8.2.1.7.3 Medical history (including allergies);

8.2.1.7.4 Education;

8.2.1.7.5 Work history;

8.2.1.7.6 Criminal justice history;

8.2.1.7.7 Substance use history, including:

8.2.1.7.7.1 Types;

8.2.1.7.7.2 Specific amount (Quantity);

8.2.1.7.7.3 Route;

8.2.1.7.7.4 Frequency of substances used;

- 8.2.1.7.7.5 Age of first use;
- 8.2.1.7.7.6 Date of last use;
- 8.2.1.7.7.7 Duration and patterns of use, including:
 - 8.2.1.7.7.7.1 All Periods of abstinence;
- 8.2.1.7.8 Past supports and resources that were effective in previous recovery attempts;
- 8.2.1.7.9 Previous treatment episodes to include type of discharge, place and date;
- 8.2.1.7.10 Reason(s) for seeking treatment;
- 8.2.1.7.11 Identification and evaluation of the client's needs;
- 8.2.1.7.12 History of other addictive disorders;
- 8.2.1.7.13 Family History including:
 - 8.2.1.7.13.1 Psychiatric history;
 - 8.2.1.7.13.2 Use of alcohol and other drugs by family members and significant others.
- 8.2.1.7.14 A diagnostic assessment summary of the client's status that addresses the client's:
 - 8.2.1.7.14.1 strengths;
 - 8.2.1.7.14.2 barriers to treatment; and
 - 8.2.1.7.14.3 goals.
- 8.2.1.7.15 Indicates which issues and areas of clinical concern are to be:
 - 8.2.1.7.15.1 Treated;
 - 8.2.1.7.15.2 Deferred; or
 - 8.2.1.7.15.3 Referred.
- 8.2.1.7.16 Includes the client's:
 - 8.2.1.7.16.1 Primary language;
 - 8.2.1.7.16.2 Attitudes toward alcohol and other drug use; and
 - 8.2.1.7.16.3 Spiritual or religious beliefs.
- 8.2.1.7.17 The rationale for placement recommendations:
 - 8.2.1.7.17.1 Signed, dated, and timed by the Counselor completing the assessment;
 - 8.2.1.7.17.2 Reviewed, as indicated by the signature (including date and time) of the clinical supervisor; and
 - 8.2.1.7.17.3 Is completed prior to the development of the initial Recovery Plan.
- 8.2.1.8 Copies of all correspondence related to the client.
- 8.2.1.9 An individualized Recovery Plan developed in partnership with the client and any identified and relevant natural supports shall be completed no later than the time required in these regulations for the modality for which the program is licensed.
 - 8.2.1.9.1 The Recovery Plan shall:
 - 8.2.1.9.1.1 Identify the date the plan is to be effective;
 - 8.2.1.9.1.2 Identify the client's:
 - 8.2.1.9.1.2.1 Strengths;
 - 8.2.1.9.1.2.2 Barriers to treatment; and
 - 8.2.1.9.1.2.3 Goals.
 - 8.2.1.9.1.3 Address the goals as derived from the assessment process:
 - 8.2.1.9.1.3.1 To be treated.
 - 8.2.1.9.1.4 Identify objectives that:
 - 8.2.1.9.1.4.1 Address the goals;
 - 8.2.1.9.1.4.2 Are specific;
 - 8.2.1.9.1.4.3 Are measurable;
 - 8.2.1.9.1.4.4 Are time limited;
 - 8.2.1.9.1.5 Specify the treatment regimen, including:
 - 8.2.1.9.1.5.1 Which services and/or activities/interventions will be used to achieve each Recovery Plan objective;
 - 8.2.1.9.1.5.2 The frequency of each service and/or activity/intervention to meet the goals/objectives;
 - 8.2.1.9.1.5.3 Goals/objectives to be referred;

8.2.1.9.1.5.4 Goals/objectives to be deferred;

8.2.1.9.1.6 Be signed and dated by:

8.2.1.9.1.6.1 The client;

8.2.1.9.1.6.2 The counselor who developed the Recovery Plan; and

8.2.1.9.1.6.3 The clinical supervisor.

8.2.1.9.1.7 The Recovery Plan shall be reviewed by the clinical supervisor to reflect any recommendations.

8.2.1.9.1.7.1 The signature of the Clinical Supervisor will ensure that the plan has been reviewed and approved with counselor and client and the recommendations on how to proceed with the case is clinically appropriate.

8.2.1.9.1.7.2 All recommendations should be completed within two (2) weeks prior to the Recovery Plan Update or not later than the plan due date.

8.2.1.10 Recovery Plan Updates

8.2.1.10.1 Recovery Plans shall be updated with the client present and any identified and relevant natural supports when clinically appropriate, and his/ her counselor, no less often than the intervals specified for the modality for which the program is licensed, or when there is a significant change in functioning.

8.2.1.10.2 The Recovery Plan Update shall address the issues remaining to be treated (including goals/objectives to be deferred/referred) as derived from the Recovery Plan.

8.2.1.10.3 The Recovery Plan Update shall reflect goals/objectives and/or activities/ interventions when there is a lack of progress or minimal engagement.

8.2.1.10.4 The Recovery Plan Update shall be reviewed by the clinical supervisor.

8.2.1.10.4.1 The signature of the Clinical Supervisor will ensure that the plan has been reviewed and approved with the counselor and client, and the recommendations on how to proceed with the case are clinically appropriate

8.2.1.10.4.2 All recommendations should be completed within two (2) weeks prior to the Recovery Plan Update or not later than the plan due date.

8.2.1.10.5 The Recovery Plan Update shall be signed and dated by:

8.2.1.10.5.1 The client;

8.2.1.10.5.2 The staff who developed the recovery plan and;

8.2.1.10.5.3 The clinical Supervisor.

8.2.1.11 Progress Notes

8.2.1.11.1 Each contact made with or on behalf of the client in accordance with the goals/objectives and interventions/activities prescribed on the recovery plan shall be documented in the client file; and

8.2.1.11.1.1 Be written to include:

8.2.1.11.1.1.1 The type(s) of service provided;

8.2.1.11.1.1.2 The date and time of the service(s) provided;

8.2.1.11.1.1.3 The length of the service(s) provided;

8.2.1.11.1.1.4 Facts

8.2.1.11.1.1.4.1 a description of the service and activity;

8.2.1.11.1.1.4.2 the client's participation in the service and/or activity;

8.2.1.11.1.1.4.3 a description of the client's response to the session

8.2.1.11.1.1.5 Clinical Impressions

8.2.1.11.1.1.5.1 the counselor's assessment of the client's response or lack of response to the service and/or activity and

8.2.1.11.1.1.5.2 the client's progress or lack of progress toward achieving the objectives prescribed in the recovery plan;

8.2.1.11.1.1.6 Plan for future sessions

8.2.1.11.1.1.6.1 anticipated implementation, by the counselor, of services and/or activities as prescribed in the recovery plan.)

8.2.1.12 Discharge Plan

8.2.1.12.1 In anticipation of successful completion or planned interruption of a client's treatment, the treatment staff and client shall jointly develop a discharge plan and document the process in the progress notes.

8.2.1.13 Discharge Summary

8.2.1.13.1 For every client that is discharged, the program shall complete a discharge summary within seventy-two (72) hours of a planned discharge and within ninety-six (96) hours of an unplanned discharge.

8.2.1.13.2 The narrative discharge summary shall include the client's:

8.2.1.13.2.1 Name;

8.2.1.13.2.2 Discharge address;

8.2.1.13.2.3 Discharge telephone number;

8.2.1.13.2.4 Admission date;

8.2.1.13.2.5 Discharge date;

8.2.1.13.2.6 A summary of the client's progress or lack of progress toward meeting recovery plan goals/objectives;

8.2.1.13.2.7 A summary of the client's participation in treatment;

8.2.1.13.2.8 The reasons for discharge;

8.2.1.13.2.9 Any unresolved issues derived from the assessment and Recovery Plan;

8.2.1.13.2.10 Recommendations and referrals regarding the need for additional services which may include: relapse prevention, social supports, medical, vocational, etc.

8.2.1.13.2.11 When the discharge is planned, the discharge summary shall be signed and dated by:

8.2.1.13.2.11.1 The client

8.2.1.13.2.11.2 The counselor who completed the discharge summary; and

8.2.1.13.2.11.3 The clinical supervisor.

8.2.1.13.2.11.3.1 The signature of the Clinical Supervisor will ensure that the plan has been reviewed and approved with counselor and client and the recommendations on how to proceed with the case is clinically appropriate

8.2.1.13.2.11.3.2 All recommendations should be completed in accordance to subsection 8.2.1.13.1.

8.3 Clinical Supervision

8.3.1 Clinical Supervision shall occur for all non-licensed clinical staff on a monthly basis.

8.3.2 For each clinical supervision session, the program will maintain documentation that includes:

8.3.2.1 The time, date and length of the meeting;

8.3.2.2 The topics covered;

8.3.2.3 The name (s) and signatures of those in attendance to include individual and group Supervision.

9.0 Facility Standards

9.1 Each agency shall provide facilities that include:

9.1.1 Privacy for communications between clients and staff members;

9.1.2 Rest rooms for clients, visitors and staff and the separation of bathroom facilities serving male and female clients.

9.1.3 Separate sleeping quarters for male and female clients (as applicable)

9.1.4 Privacy for personal hygiene (as applicable);

9.1.5 Secure closet and storage space for clients' personal property, security with lock and key

9.1.6 Reasonably private access to a telephone (as applicable);

9.1.7 Laundry facilities and supplies (as applicable);

9.1.8 Space for solitude;

9.1.9 Programs shall ensure housekeeping services are provided in addition to whatever chores residents may be required to perform.

9.1.9.1 Resident of inpatient facilities can assist with IADL's only when indicated on the Recovery Plan (as applicable).

9.1.9.2 An updated Recovery plan will need to include all IADL's

- 9.2 Agencies shall maintain up-to-date documentation verifying that they have a certificate of occupancy and meet applicable federal, state and local building, zoning, fire, and safety and accessibility requirements.
- 9.3 Agencies shall maintain facilities in neat and clean condition, and eliminate any hazardous conditions that endanger the health or safety of clients, visitors or staff.
- 9.4 Agencies shall post a current fee schedule in a public place within the facility.
- 9.5 Agencies shall post hours of operation in a public place within the facility.
- 9.6 Fire Prevention and Safety
 - 9.6.1 Agencies shall display up to date certificates or approval/inspection by Fire Department authorities whenever this is required/available in the specific community where the program is located.
 - 9.6.2 Programs shall document fire drills and other emergency drills completed:
 - 9.6.2.1 On a monthly basis for all residential facilities on varied shifts throughout the year, or according to more stringent accreditation standards if the program is accredited.
 - 9.6.2.2 On a quarterly basis for all outpatient facilities or according to more stringent accreditation standards if the program is accredited
- 9.7 Emergency policies and procedures.
 - 9.7.1 Each agency shall establish a plan of action in the event of emergencies or disasters, based on the program's capability and limitations. The plan shall include provisions:
 - 9.7.1.1 For responding to severe weather, loss of power or water or other natural disaster;
 - 9.7.1.2 For evacuation plans with specific primary and alternative evacuation routes;
 - 9.7.1.3 For posting evacuation routes in areas visible to staff, clients and visitors;
 - 9.7.1.4 For responding to accidents that result in injury or death;
 - 9.7.1.5 Governing how available resources will be used to continue client care;
 - 9.7.1.6 Governing how the program will effectively activate community resources to prevent or minimize the consequences of a disaster;
 - 9.7.1.7 Concerning staff preparedness and the designation of roles and functions;
 - 9.7.1.8 Concerning criteria for the cessation of nonessential services and client transfer determinations; and
 - 9.7.1.9 Governing how it will protect the safety of clients and staff and the security of its records.
 - 9.7.2 All treatment programs shall develop procedures for handling a client who is exhibiting behavior that is threatening to the life or safety of the client or others.
 - 9.7.3 All treatment programs shall have a staff member on site at all times trained in:
 - 9.7.3.1 Crisis intervention; and
 - 9.7.3.2 The standard Red Cross first aid class and CPR certification, or its equivalent.

10.0 Food Services

- 10.1 A written plan for meeting the basic nutritional, as well as any special dietary needs of clients. Plans and menus shall include at a minimum:
 - 10.1.1 A varied and nutritious diet of three (3) meals per-day, seven (7) days per-week;
 - 10.1.2 Snacks as part of the overall dietary plan;
 - 10.1.3 Food substitutions, as applicable; and
 - 10.1.4 Be reviewed by a registered dietitian at least annually, and whenever menus are substantially changed.
- 10.2 Programs that employ food services staff shall ensure these staff have appropriate experience and qualifications when beginning employment; or contract for food services with a commercial food service company to operate the facility's services.
- 10.3 Programs, with the exception of inpatient programs, may provide opportunities for residents to work in the food service on a volunteer basis only if it is done as part of a structured vocational training program approved by the Division.
 - 10.3.1 Residents of inpatient facilities can assist with food services only when indicated on the Recovery Plan (as applicable).
 - 10.3.2 An updated Recovery plan will need to include food services (as applicable).
- 10.4 Programs may not mandate payment for meal plans as a treatment requirement.
- 10.5 Programs may provide opportunities for residents to work in the janitorial and maintenance service areas on a volunteer basis only if it is done as part of the resident's treatment and included on the recovery plan. These opportunities shall not be offered in inpatient programs.

Part III: Specific Standards Applicable to Categories of Programs

11.0 Ambulatory Withdrawal Management with Extended Onsite Monitoring (ASAM Level 2-WM and ASAM Level 2-WM-23 hour)

11.1 ASAM Level 2-WM

11.1.1 In addition to the requirements applicable to all programs, an ASAM Level 2-WM program shall:

11.1.1.1 Have medical, nursing, counseling, and other support staff necessary to provide services appropriate to the diagnostic, withdrawal management, and behavioral health/bio-psychosocial needs of individuals being admitted to the program. This includes:

11.1.1.1.1 A designated medical director available on call at all times, as allowed under law.

11.1.1.1.2 A designated prescriber available on site or for consultation at least 10 hours per week;

11.1.1.1.3 A physician's assistant (PA), NP, or APRN, licensed as physician extenders, may perform duties designated by a physician within their scope of practice.

11.1.1.1.4 At least one nurse (NP, RN, LPN) available on site at least 10 hours per week

11.1.1.1.5 Licensed practitioners or unlicensed counselors with direct supervision on site;

11.1.2 Meet the following requirements for screening, assessment, and Recovery Planning:

11.1.2.1 Individual counseling that shall include at least one (1) sixty (60) minute counseling session per week by a LBHP or unlicensed counselor.

11.1.2.2 Daily counseling contact by a LBHP or unlicensed counselor that shall include at a minimum:

11.1.2.2.1 One (1) fifteen (15) minute face-to-face or phone contact to:

11.1.2.2.1.1 Engage the client;

11.1.2.2.1.2 Help the client cope with withdrawal; and

11.1.2.2.1.3 Continue in ongoing treatment services.

11.1.2.3 Group Counseling that shall include at least two (2) ninety (90) minute counseling sessions per week

11.1.2.4 Urine drug screens are required upon admission and as directed by the Recovery Plan.

11.1.2.5 Laboratory tests including serology and other tests deemed necessary by the program physician.

11.1.2.6 A biological test for pregnancy for all women of child-bearing age.

11.1.2.7 HIV testing should be encouraged, and conducted with the client's signed consent.

11.1.2.8 Nursing assessment and behavioral health assessment at time of admission that is reviewed by a physician to determine need for withdrawal management, eligibility, and appropriateness for admission and referral.

11.1.2.9 A medical care plan within 24 hours of admission based on the findings of a physical examination (completed prior to admission or on site by psychiatric medical staff or nursing staff), including a brief screening to identify motivation for treatment, relapse potential, and recovery environment at discharge. The medical plan shall be reviewed by a physician and shall be filed in the individual's record and updated as needed.

11.1.2.10 Initial Recovery Plan completed within 24 hours of admission, and comprehensive Recovery Plan completed within seven days of admission.

11.1.2.11 Updates to Recovery Plan every seven days.

11.1.2.12 Methadone and buprenorphine/naloxone must be available for use with opiate withdrawal as preferred medications. Opioid withdrawal with medications must follow Federal and State guidelines under 42 CFR section §8.12. This section also references orientation once a client is admitted.

11.1.2.13 Discharge/transfer planning begins at admission. An initial discharge plan is developed at time of admission, while a comprehensive discharge plan is complete at discharge.

11.1.2.14 Referral and assistance as needed for the client to gain access to other needed Medicaid SUD or mental health services.

11.1.2.15 The program shall implement the withdrawal management/Recovery Plan and document the client's response to and/or participation in scheduled activities. Notes shall include:

11.1.2.15.1 The individual's physical condition, including vital signs.

11.1.2.15.2 The individual's mood and behavior.

11.1.2.15.3 Statements about the individual's condition and needs.

11.1.2.15.4 Information about the individual's progress or lack of progress in relation to withdrawal management/treatment goals.

11.1.2.15.5 Additional notes shall be documented, as needed.

11.1.2.16 Physician orders are required for medical and psychiatric management.

11.2 ASAM Level 2-WM-23 Hour

11.2.1 In addition to the requirements applicable to all programs, an ASAM Level 2-WM- 23 Hour program shall:

11.2.1.1 Have the ability to accept admissions at any time, and operate 24 hours per-day, seven (7) days per-week.

11.2.1.2 Have medical, nursing, counseling, and other support staff necessary to provide services appropriate to the diagnostic, withdrawal management, and behavioral health/bio-psychosocial needs of individuals being admitted to the program. This includes:

11.2.1.2.1 A designated prescriber with on-call availability 24/7 for consultation and in order to discharge clients to higher levels of care if necessary;

11.2.1.2.2 A physician's assistant (PA), NP, or APRN, licensed as physician extenders, may perform duties designated by a physician within their scope of practice.

11.2.1.2.3 At least one nurse (NP, RN, and LPN) per 12 clients on site at all times.

11.2.1.2.4 One behavioral health technician per 12 clients on site at all times.

11.2.1.3 Meet the following requirements for screening, assessment, and Recovery Planning:

11.2.1.3.1 Urine drug screens are required upon admission and as directed by the Recovery Plan.

11.2.1.3.2 A biological test for pregnancy for all women of child-bearing age.

11.2.1.3.3 Nursing assessment and behavioral health assessment at time of admission that is reviewed by a physician to determine need for withdrawal management, eligibility and appropriateness for admission and referral.

11.2.1.3.4 Initial Recovery Plan completed plan at admission.

11.2.1.3.5 Methadone and buprenorphine/naloxone must be available for use with opiate withdrawal as preferred medications. Opioid withdrawal with medications must follow State and Federal guidelines.

11.2.1.3.6 Discharge/transfer planning begins at admission. An initial discharge plan is developed at time of admission, while a comprehensive discharge plan is complete at discharge.

11.2.1.3.7 If the individual steps down to ASAM Level 2-WM, then all screening, assessment, and Recovery Plan documentation must be completed consistent with ASAM Level 2-WM.

11.2.1.3.8 Referral and assistance as needed for the client to gain access to other needed SUD or mental health services.

11.2.1.3.9 The program shall implement the withdrawal management/Recovery Plan and document the individual's response to and/or participation in scheduled activities. Notes shall include:

11.2.1.3.9.1 The individual's physical condition, including vital signs.

11.2.1.3.9.2 The individual's mood and behavior.

11.2.1.3.9.3 Statements about the individual's condition and needs.

11.2.1.3.9.4 Information about the individual's progress or lack of progress in relation to withdrawal management/treatment goals.

11.2.1.3.9.5 Additional notes shall be documented, as needed.

11.2.1.3.10 Physician orders are required for medical and psychiatric management.

12.0 Outpatient Substance Use Disorder Services (ASAM Level 1)

12.1 In addition to the requirements applicable to all programs, an ASAM Level 1 program shall:

12.1.1 Provide fewer than nine contact hours per week.

12.1.2 Include professionally directed assessment, diagnosis, treatment, and recovery services provided in an organized non-residential treatment setting.

12.1.3 Provide services including, but not limited to individual, group, family counseling and psychoeducation on recovery, and wellness.

12.1.4 Provide an array of licensed practitioners, unlicensed counselors, certified peers, and credentialed behavioral health technicians operating within their scope of practice.

12.1.5 Ensure caseload sizes are based on needs of individuals actively engaged in services to ensure effective, individualized treatment, and rehabilitation.

- 12.1.6 Ensure Clinical Supervisors or QHP's are on site or available for phone consultation in a crisis 24/7.
- 12.1.7 Meet the following requirements for screening, assessment, and Recovery Planning:
 - 12.1.7.1 For individuals new to the program, a comprehensive bio-psychosocial assessment shall be completed within seven (7) days of admission which substantiates appropriate client placement and
 - 12.1.7.2 The assessment will need to be reviewed and signed by either the Clinical supervisor, QHP, or QMP.
 - 12.1.7.3 For the position of Clinical Supervisor reference 6.3-6.3.1.4 of these regulations for the position identified "Qualification for Clinical Supervisor" when signing off on an assessment.
 - 12.1.7.4 Individualized, interdisciplinary Recovery Plan shall be completed within thirty (30) days of admission or by the fourth counseling session, whichever occurs first. This plan should be developed in collaboration with the individual to include any relevant natural supports.
 - 12.1.7.5 The Recovery Plan shall be reviewed and updated in collaboration with the individual as needed based on changes in functioning, or at a minimum of every ninety (90) days.
 - 12.1.7.6 Physical examination by a qualified medical professional within 90 days prior to admission or documentation of good faith effort in referring the client for a physical and/or efforts made to obtain documentation of a physical.
 - 12.1.7.7 Discharge and Transfer planning shall begin at admission.

13.0 Intensive Outpatient Treatment (ASAM Level 2.1)

- 13.1 In addition to the requirements applicable to all programs, an ASAM Level 2.1 program shall:
 - 13.1.1 Provide nine (9) or more contact hours of clinically intensive programming per week (not to exceed):
 - 13.1.1.1 20 hours per week for adults, age 18 years and older, with a minimum of three (3) days per week and based on individual Recovery Plans.
 - 13.1.2 Include professionally directed assessment, diagnosis, treatment, and recovery services provided in an organized, non-residential treatment setting.
 - 13.1.3 Provide services including, but not limited to individual, group, family counseling, and psychoeducation on recovery, as well as monitoring of drug use, and orientation to community-based support groups. Any relevant and needed medical, psychological, psychiatric, laboratory and toxicology services can be made available through consultation or referral.
 - 13.1.4 Include the use of evidence-informed practices, such as CBT, motivational interviewing, and multidimensional family therapy.
 - 13.1.5 Provide an array of licensed practitioners, unlicensed counselors, and credentialed behavioral health technicians operating within their scope of practice.
 - 13.1.5.1 Clinical Supervisors, QHPs, Or QMP's on site at least 10 hours per week during hours of operation, available for phone consultation at all times.
 - 13.1.5.2 For the position of Clinical Supervisor reference 6.3-6.3.1.4 of these regulations for the position identified "Qualification for Clinical Supervisor" regarding onsite qualifications.
 - 13.1.5.3 Caseload size shall be based on needs of individuals actively engaged in services to ensure effective, individualized treatment and rehabilitation.
 - 13.1.6 Meet the following requirements for screening, assessment, and Recovery Planning:
 - 13.1.6.1 For individuals new to the program, a comprehensive bio-psychosocial assessment shall be completed within 72 hours of admission which substantiates appropriate client placement.
 - 13.1.6.1.1 The assessment shall be reviewed and signed by the Clinical Supervisor, QHP or QMP.
 - 13.1.6.1.2 For the position of Clinical Supervisor reference 6.3-6.3.1.4 of these regulations for the position identified Qualification for Clinical Supervisor when signing off.
 - 13.1.6.2 Physical examination by a qualified medical professional shall be completed within a reasonable time, as determined by the client's medical condition, not to exceed 90 days prior to admission, or documentation of good faith effort in referring the client for a physical and/or efforts made to obtain documentation of a physical.
 - 13.1.6.3 Individualized, interdisciplinary recovery plan shall be completed within 72 hours of admission. This plan should be developed in collaboration with the individual.
 - 13.1.6.4 Recovery plan shall be reviewed and updated in collaboration with the individual and relevant natural supports as needed based on changes in functioning, or at a minimum of every thirty (30) days.

- 13.1.6.5 Discharge and transfer planning shall begin at admission.
- 13.1.6.6 Referral and assistance shall be provided as needed for the client to gain access to other needed addiction or mental health services.

14.0 Partial Hospitalization Program (ASAM Level 2.5)

- 14.1 In addition to the requirements applicable to all programs, an ASAM Level 2.5 program shall:
 - 14.1.1 Provide 20 or more hours of clinically intensive programming per week for adults, age 18 years and older, at a minimum of three days per week and based on individual recovery plans
 - 14.1.2 Have a procedure describing how the program will address the psychiatric or medical emergencies, urgent or routine psychiatric or medical needs, and lab services that may be required as a result of those psychiatric or medical services.
 - 14.1.3 Provide comprehensive bio-psychosocial assessments and individualized treatment, and allow for a valid assessment of dependency.
 - 14.1.4 Provides for frequent monitoring and management of the client's medical and emotional concerns in order to avoid hospitalization.
 - 14.1.5 Provide services including, but not limited to individual, group, family counseling, and psychoeducation on recovery, as well as monitoring of drug use, medication management, medical, and psychiatric examinations, crisis intervention coverage, and orientation to community-based support groups.
 - 14.1.6 Include the use of evidence-informed practices, such as CBT, motivational interviewing, and multidimensional family therapy.
 - 14.1.7 Provide an array of licensed practitioners, unlicensed counselors, certified peers and credentialed behavioral health technicians operating within their scope of practice. This includes:
 - 14.1.7.1 A physician, NP or PA shall be part of the interdisciplinary team and be available on site or for phone consultation at all times of program operations
 - 14.1.7.2 Supervisors (QHPs) on site at least 10 hours per week during hours of operation, available for phone consultation at all times.
 - 14.1.7.3 Caseload size shall be based on needs of individuals actively engaged in services to ensure effective, individualized treatment and rehabilitation. Therapeutic groups shall not exceed 15 individuals;
 - 14.1.8 Meet the following requirements for screening, assessment, and Recovery Planning:
 - 14.1.8.1 For individuals new to the program, a comprehensive bio-psychosocial assessment shall be completed within 72 hours of admission which substantiates appropriate client placement. This assessment shall be reviewed and signed by a qualified professional.
 - 14.1.8.2 Physical examination by a qualified medical professional shall be completed within a reasonable time, as determined by the client's medical condition, not to exceed 90 days prior to or after admission, or documentation of good faith effort in referring the client for a physical and/or efforts made to obtain documentation of a physical.
 - 14.1.8.3 Individualized, interdisciplinary recovery plan shall be completed within 72 hours of admission. This plan should be developed in collaboration with the individual.
 - 14.1.8.4 Recovery plan shall be reviewed and updated in collaboration with the individual as needed based on changes in functioning, or at a minimum of every 30 days.
 - 14.1.8.5 Discharge/transfer planning shall begin at admission.
 - 14.1.8.6 Referral and assistance shall be provided as needed for the beneficiary to gain access to other needed SUD or mental health services.

15.0 Opioid Treatment Programs (ASAM Level 1)

- 15.1 In addition to the requirements applicable to all programs, an ASAM Level 1 Opioid Treatment Program shall:
 - 15.1.1 Be in full compliance with Federal and State Regulations regarding Opioid treatment.
 - 15.1.2 Conform to the Federal and state opioid treatment standards set forth under 42 C.F.R. 8.12 in order to provide Subutex and Suboxone for opioid maintenance and detoxification. These regulations require that OTPs provide medical, counseling, drug abuse testing, and other services to clients admitted to treatment. To offer Subutex and Suboxone, OTPs need to modify their registration with the DEA to add Schedule III narcotics to their registration certificates.
- 15.2 In addition to the admission procedures described in these regulations:

15.2.1 If an applicant for Opioid treatment services has been discharged within seven (7) years from treatment at another OTP, the admitting program shall document that a good faith effort was made to review whether or not the client is enrolled in any other OTP. The confirmation and verification of past or current enrollment shall be documented in the client record.

15.2.1.1 This is to include programs within 100 miles of the program in accordance to 42CFR §8.12 (G)

15.2.2 A client enrolled in another program shall not be permitted to enroll in treatment in any other OTP except in exceptional circumstances as determined by the medical director. Exceptions shall be:

15.2.2.1 Noted in the client's record.

15.2.2.2 Special admission populations (where the absence of physiological dependence shall not be an exclusion criterion with a clinically justifiable admission) shall include:

15.2.2.2.1 Persons recently released from a penal institution; (within six (6) months after release.)

15.2.2.2.2 Pregnant clients; (Program physician shall certify pregnancy)

15.2.2.2.3 Previously treated clients; (Up to two (2) years after discharge)

15.2.2.2.4 Adolescents provided that:

15.2.2.2.4.1 Individuals under the age of 18 have had two documented attempts at short-term medically supervised withdrawal (detoxification) or drug-free treatment to be eligible for maintenance treatment;

15.2.2.2.4.2 In addition to the consent of the client, Individuals under 18 years old, unless otherwise permitted by 16 Del.C. §2210 to consent to treatment have had a parent or legal guardian complete and sign the agency's consent to OTP Treatment.

15.3 Staffing Requirements

15.3.1 OTP programs shall include an array of licensed practitioners, unlicensed counselors, RNs/LPNs, certified peers and behavioral health technicians operating within their scope of practice.

15.3.2 Clinical Supervisors or QHP, shall be on site or available for phone consultation in a crisis 24/7. OTPs must conform to the Federal opioid treatment standards set forth under 42 C.F.R.

15.3.2.1 For the position of Clinical Supervisor reference 6.3-6.3.1.4 of these regulations for the position identified "Qualification for Clinical Supervisor".

15.3.2.2 OTPs shall develop staffing models consistent with these federal regulations and shall have an adequate number of physicians, nurses, counselors, and other staff for the level of care provided and the number of clients enrolled in the program.

15.3.2.3 OTPs shall determine staffing patterns by taking into account the characteristics and needs of particular client populations.

15.3.2.4 Client-to-staff ratios should be sufficient to ensure that clients have reasonable and prompt access to counselors and receive counseling services at the required levels of frequency and intensity.

15.3.3 A designated medical director shall be available on site or for consultation at all times the facility is open.

15.4 Screening, Assessment, and Recovery Planning

15.4.1 Nursing assessment shall be completed at time of admission and be reviewed by a physician to determine need for opioid treatment services, eligibility, and appropriateness (proper client placement) for admission and referral.

15.4.2 For individuals new to the program, a comprehensive bio-psychosocial assessment per Title 16 Delaware Administrative Code 6001 shall be completed within 72 hours of admission which substantiates appropriate patient placement. This assessment must be reviewed, signed, and dated by a QHP or QMP.

15.4.3 Per 42 CFR Part 8, a fully documented physical evaluation by a program physician or a primary care physician, or an authorized healthcare professional (e.g., APRN or physician assistant licensed to provide physical exams under their scope of practice as defined under Delaware law) under the supervision of a program physician shall be completed prior to admission. The full medical examination, including the results of serology and other tests, shall be completed within 14 days following admission.

15.4.4 An initial Recovery Plan shall be developed within 72 hours of admission.

15.4.5 Individualized, interdisciplinary Recovery plan shall be completed within thirty (30) days. The plan must be client-centered and developed in collaboration with the client and include an appropriate regimen of methadone or buprenorphine at a dose established by a physician or licensed supervisee.

15.4.5.1 The medication regime must be reviewed and modified as the client becomes stable and throughout treatment.

15.4.6 The recovery plan shall be reviewed and updated in collaboration with the client as needed based on changes in functioning, or at a minimum of every ninety (90) days.

15.4.7 Discharge and transfer planning shall begin at admission.

15.4.8 Referral and assistance shall be provided as needed for the client to gain access to other needed SUD or mental health services.

15.5 Client Orientation

15.5.1 In addition to the requirements described in these regulations, OTPs shall inform clients of:

15.5.1.1 The facts concerning the use of methadone, buprenorphine, or other Opioid treatment medications dispensed by the program, including, but not limited to:

15.5.1.1.1 An explanation of the interaction between the Opioid treatment medication(s) dispensed by the program and other medications, medical procedures and food;

15.5.1.1.2 Any potential adverse reactions, including those resulting from interactions with other prescribed or over-the-counter pharmacological agents, other medical procedures and food;

15.5.1.1.3 The importance of notifying the client's primary care physician of their admission to and discharge from the program;

15.5.1.2 The facts concerning the withdrawal from the use of methadone, buprenorphine, or other Opioid treatment medications dispensed by the program, including, but not limited to:

15.5.1.2.1 Policies and procedures regarding voluntary, involuntary, and against medical advice withdrawal from Opioid treatment medications;

15.5.1.2.2 An explanation of the potential interaction between withdrawal from the Opioid treatment medication(s) dispensed by the program and other medications, and medical procedures;

15.5.1.2.3 Any potential adverse reactions as a result of withdrawal from Opioid treatment medications, including those resulting from interactions with other prescribed or over-the-counter pharmacological agents, other medical procedures; and

15.5.1.2.4 The importance of notifying the client's primary care physician of withdrawal from the program.

15.5.1.3 The program's drug-screening procedure;

15.5.1.4 The program's Opioid treatment medication dispensing procedure, including the days and hours of operation.

15.5.1.5 The program's rules including non-compliance, and discharge procedures, to include administrative Opioid treatment medication withdrawal;

15.5.1.6 The signs and symptoms of overdose and when to seek emergency assistance;

15.5.1.7 The emergency procedures maintained by the program as required in these regulations shall be available twenty-four (24) hours per day.

15.5.1.8 Safe storage practices for take-home Opioid treatment medications;

15.5.1.9 The financial aspects of treatment, including the consequences of nonpayment of required fees.

15.5.2 Upon admission, the program shall obtain from or issue to each client a photo identification card.

15.6 Client Re-admissions

15.6.1 A client re-admitted to the same program within thirty (30) days need not receive a medical examination and laboratory tests if s/he received a medical examination and laboratory tests within the previous year.

15.7 Hours of Operation, Staffing, and Staff Orientation

15.7.1 OTPs shall operate six (6) days per week, with at least two (2) hours of medicating time accessible daily outside the hours of 8 a.m. to 5 p.m. Monday through Friday, and three (3) hours on Saturday or Sunday.

15.7.2 Each OTP shall post medication dispensing and counseling hours in a public place within the facility.

15.7.3 Each OTP shall have the services of licensed medical personnel including:

15.7.3.1 A designated medical director, who is a physician, responsible for the administration of all medical services performed by the program and for compliance with all federal, state and local laws, rules and regulations regarding medical treatment of narcotic dependence;

15.7.4 At all times when the clinic is open, if a physician is not on site, a physician shall be available for consultations and emergency attendance;

15.7.5 Prior to services delivery, in addition to training requirements in subsection 5.1.7.1, OTPs shall provide new staff orientation, including:

15.7.5.1 Clinical and pharmacotherapy issues,

15.7.5.2 Overdose, and other emergency procedures.

15.7.5.3 Provision of services to special populations such as adolescents, pregnant women, and senior citizens.

15.8 Administration of Opioid Treatment Medication

15.8.1 No dose of Opioid treatment medication shall be administered until the client has been identified and the dosage compared with the currently ordered and documented dosage level.

15.8.2 Only a licensed professional authorized by law may administer or dispense Opioid treatment medication.

15.8.3 Ingestion shall be observed and verified by the personnel authorized to administer the Opioid treatment medication.

15.8.4 There shall be only one client in the dispensing area at a time.

15.8.5 A physician shall obtain a detailed history of drug use within the last twenty-four (24) hours prior to initial dose, and,

15.8.5.1 Determine the client's initial dosage after a physical examination;

15.8.5.2 The initial dose of Methadone shall not exceed thirty (30) mg;

15.8.5.3 Additional medication shall not be administered, unless:

15.8.5.3.1 After three (3) hours of observation, the physician documents in the client's record that the initial dose did not suppress opiate abstinence symptoms; and

15.8.5.3.2 The physician writes orders for additional medication.

15.8.5.4 The initial total daily dose of methadone for the first day shall not exceed forty (40) milligrams (mg), unless the physician documents justification for a higher dosage in the client record that forty (40) mg did not suppress opiate abstinence symptoms.

15.8.5.5 The initial dose of any other Opioid treatment medications shall not exceed federal regulations, guidelines or medical protocol.

15.8.5.6 The program physician shall justify any deviations from dosages, frequencies, and conditions of usage described in the approved product labeling.

15.8.5.7 Qualified medical personnel shall determine all subsequent dosage levels and shall:

15.8.5.7.1 Document each order change on the physician's medication orders;

15.8.5.7.2 Sign and date each order change

15.8.6 Programs shall dispense methadone in an oral form, in accordance with federal and state law and regulations in containers conforming to 42 CFR (Part VIII) Section 12.(i)(5).

15.8.7 Any Opioid treatment medication error or adverse drug reaction shall be reported promptly to the medical director and an entry made in the client's record.

15.8.8 The medical director shall ensure that significant adverse drug reactions are reported to the Federal Food and Drug Administration and to the manufacturer in a manner that does not violate the client's confidentiality.

15.8.9 Each program shall develop a written emergency procedure to be implemented in the case of an employee strike, fire or other emergency situation that would stop or substantially interfere with normal dispensing operations. The emergency procedure shall comply with subsection 9.3 and also include:

15.8.9.1 Arrangements with a security provider for immediate security of Opioid treatment medications;

15.8.9.2 Written agreements, updated annually, with back-up licensed professionals authorized by law, for the coverage of dispensing and other medical needs if regular personnel are not available;

15.8.9.3 A reliable system for confirming the identities of clients before dispensing; and

15.8.9.4 Written agreements, updated annually, for the use of an alternate program, hospital or other site for dispensing during an emergency period.

15.9 Opioid Treatment Medication Schedules; Unsupervised or "Take-home Use"

15.9.1 Treatment program decisions on dispensing unsupervised or "take-home" medications shall be determined by the medical director. The medical director shall consider the following criteria to determine whether a patient is responsible in handling drugs for unsupervised use:

15.9.1.1 Regularity of Program attendance;

15.9.1.2 Absence of recent abuse of drugs, including alcohol;

15.9.1.3 Regularity of clinic attendance;

15.9.1.4 Absence of serious behavioral problems at the clinic.

15.9.1.5 Absence of known recent criminal activity (e.g. drug and drug related arrests, etc...)

15.9.1.6 Progress in Meeting Recovery Plan Goals;

- 15.9.1.7 Responsibility in the handling, and plan for the safe storage, of take home Opioid treatment medications;
- 15.9.1.8 Stability of the client's home environment and social relationships.
- 15.9.1.9 When it is determined that a patient is responsible in handling Opioid drugs, the Federal Regulations for take home privileges shall be applied;
- 15.9.2 OTPs shall maintain current procedures adequate to identify the theft or diversion of take-home medications, including:
 - 15.9.2.1 Labeling containers with the OTP's name, address, and telephone number; and
 - 15.9.2.2 Requiring patients to come to the clinic on a randomly scheduled basis for drug testing and checking the amount of take-home medication used to that point.
 - 15.9.2.3 Programs shall also ensure that take-home supplies are packaged in a manner that is designed to reduce the risk of accidental ingestion, including child-proof containers.
- 15.10 Revocation of Take-home Privileges
 - 15.10.1 The program medical director will determine if a client's conduct warrants revocation or suspension of take-home privileges.
 - 15.10.2 Documentation of the rationale for revoking or suspending take-home privileges will be entered into the client's record by the medical director.
- 15.11 Exceptions
 - 15.11.1 Must be extended in accordance with Federal Law, 42 CFR, 8.11 ("Exception Report and Record of Justification").
 - 15.11.2 If, in the judgment of the program physician:
 - 15.11.2.1 A client has a physical disability that interferes with his or her ability to conform to the applicable mandatory attendance schedule; the program physician may permit a reduced attendance schedule.
 - 15.11.2.2 A client is unable to conform to the applicable mandatory attendance schedule because of exceptional circumstances such as illness, personal or family crises, travel, or other hardship, the program physician may permit a temporarily reduced schedule, provided that the client is responsible in handling Opioid treatment medications. In such cases, the program physician shall record or verify the rationale for the exception in the client's record and date and sign the record.
 - 15.11.2.3 Employed clients may apply for an exception to these requirements if the dispensing hours of the clinic conflict with working hours of the client. In such cases, the client may receive take-home medications after verifying work hours through reliable means, provided that the physician documents reasons for permitting take home medication.
 - 15.11.3 Decisions regarding all "take-home" medication exceptions must comply with Federal and State Regulations (DHSS and SAMHSA), 42 CFR Part 8, subsection 8.12 (H) "Federal opioid treatment standards.
 - 15.11.4 Any client who transfers from one (1) OTP to another shall be eligible for placement on the same take-home schedule. Before initiating take-home privileges for a client transferring from other maintenance treatment programs, the program physician shall document reasons for permitting take home medication.
- 15.12 Voluntary Medical withdrawal from Opioid treatment Medication
 - 15.12.1 Voluntary medical withdraws from Opioid treatment medication shall include:
 - 15.12.1.1 A request signed and dated by the client, for voluntary medication withdrawal.
 - 15.12.1.2 Documentation of the physician's rationale for initiation of withdrawal.
 - 15.12.1.3 Documentation of the physician's rationale for continuing the withdrawal if there is any change in the physician's orders.
 - 15.12.1.4 Documentation signed and dated by the client that the withdrawal will be discontinued and maintenance resumed at the client's request.
 - 15.12.1.5 A biological test for pregnancy for all women of child-bearing age prior to the initiation of withdrawal.
 - 15.12.1.6 Revision of the Recovery Plan with an increase in counseling and other support services in relation to medication dosage changes.
 - 15.12.1.7 Provisions for continuing care after the last dose of Opioid treatment medication.
- 15.13 Withdrawal Against Medical Advice
 - 15.13.1 Withdrawal against medical advice shall include:

- 15.13.1.1 Documentation of all efforts taken by staff members to discourage initiation and continuation of withdrawal against medical advice.
- 15.13.1.2 Documentation of the reasons the client is seeking withdrawal against medical advice.
- 15.13.1.3 Involuntary withdrawal:
- 15.13.1.4 Involuntary withdrawal from an Opioid treatment medication shall be conducted in accordance with a dosage reduction schedule prescribed by the physician.
- 15.13.1.5 Clients being involuntarily discharged shall be referred to other treatment, as clinically indicated.
- 15.13.1.6 OTPs shall document the reasons for initiation of involuntary withdrawal in the client's record.
- 15.13.1.7 Prior to the beginning of involuntary withdrawal, efforts should be documented regarding referral or transfer of the client to a suitable, alternative treatment program.
- 15.13.1.8 Involuntary withdrawal shall be considered a planned discharge and shall comply with subsection 8.6 regarding the planned discharge of a client.
- 15.13.1.9 Documentation during withdrawal shall include:
 - 15.13.1.9.1 Documentation by the physician of the schedule for withdrawal and any changes made to the schedule by the physician during the withdrawal.
 - 15.13.1.9.2 Counseling designed to promote the continuation of services following withdrawal.

15.14 Detoxification Treatment

- 15.14.1 An OTP shall maintain procedures that are designed to ensure that qualified medical personnel admit clients to short- or long-term detoxification treatment.
- 15.14.2 Patients with two or more unsuccessful detoxification episodes within a twelve (12) month period shall be assessed by the OTP physician for other forms of treatment.
- 15.14.3 A program shall not admit a client for more than two (2) detoxification treatment episodes in one year.

15.15 Pregnant Clients

- 15.15.1 In addition to the other requirements of this section, for pregnant clients the following shall apply:
 - 15.15.1.1 OTPs shall provide priority in initiating treatment.
 - 15.15.1.2 The physician shall document in the client record all clinical findings supporting the certification of the pregnancy prior to the administration of an initial dose of Opioid treatment medication.
 - 15.15.1.3 The initial dose of Methadone shall not exceed 40 mg.
 - 15.15.1.4 The program physician shall evaluate dosing of pregnant women weekly during the last trimester of the pregnancy.
 - 15.15.1.5 If there is simultaneous use of alcohol and/or other drugs the program shall document:
 - 15.15.1.5.1 Education of the client regarding the potential impact of substance use on the fetus.
 - 15.15.1.5.2 Attempts to encourage the client to cease use of substances other than those prescribed by a physician.
 - 15.15.1.5.3 Referrals made to appropriate levels of care.
 - 15.15.1.6 Pregnant clients shall be given the opportunity for prenatal care either by the program or by referral to appropriate health care providers.
 - 15.15.1.7 The program shall document all attempts to assist the client with obtaining prenatal care.
 - 15.15.1.8 The program shall offer prenatal instruction on:
 - 15.15.1.8.1 Education on fetal development;
 - 15.15.1.8.2 Care for the newborn;
 - 15.15.1.8.3 Breastfeeding;
 - 15.15.1.8.4 Effects of maternal drug use on the fetus;
 - 15.15.1.8.5 Information on parenting;
 - 15.15.1.8.6 Importance of sound maternal nutritional practices.
 - 15.15.1.9 OTP's shall give priority to pregnant women seeking admission to treatment.
 - 15.15.1.10 OTP's shall maintain current policies and procedures that reflect the special needs of patients who are pregnant. Prenatal and other gender specific services shall be provided either by the OTP or by referral to appropriate health care providers.
 - 15.15.1.11 Medical withdrawal of the pregnant, Opioid - addicted woman from Opioid treatment medication is not indicated or recommended. No pregnant client shall be involuntarily medically withdrawn from an Opioid treatment medication.

- 15.15.1.12 Pregnant individuals who choose to withdraw from treatment against medical advice shall do so under the direct supervision of the program physician in conjunction with an obstetrician who can monitor the effects on the fetus.
- 15.15.1.13 If a pregnant client refuses direct treatment, referral for treatment, or referral for other services, the program physician shall have the client acknowledge said refusal in writing. Documentation of the refusal shall be recorded in the client's record.
- 15.15.1.14 The program physician shall request the physician, hospital, or program to which the individual is referred, to provide reports of prenatal care and a summary of the delivery and treatment outcome for the client and baby. Documentation of the request(s) shall be included in the client's record.
- 15.15.1.15 Within three (3) months after termination of the pregnancy, the program physician shall evaluate the individual's treatment status and document whether she should remain in the comprehensive maintenance program or be detoxified.

15.16 Accreditation

- 15.16.1 Programs shall be accredited by an accreditation body approved by The Substance Abuse and Mental Health Services Administration (SAMHSA) and registered with the Drug Enforcement Agency (DEA), as required.

16.0 Clinically Managed Residential Withdrawal Management (ASAM Level 3.2-WM)

16.1 In addition to the requirements applicable to all programs, an ASAM Level 3.2-WM program shall:

- 16.1.1 Provide services in an organized, residential, non-medical setting by an appropriately trained staff that provides safe, 24-hour medication monitoring observation and support in a supervised environment. The program emphasis is on peer support, not medical and nursing care.
- 16.1.2 Have an interdisciplinary team of appropriately trained clinicians, such as physicians, nurses, counselors, social workers, and psychologists available to assess and treat the client and to obtain and interpret information regarding the client's needs. The team also includes unlicensed counselors and credentialed behavioral health technicians operating within their scope of practice to provide services appropriate to the bio-psychosocial needs of clients. The number and disciplines of team members are appropriate to the range and severity of the individual's problems. This includes:
 - 16.1.2.1 A designated medical director on call at all times.
 - 16.1.2.2 A psychiatrist, psychiatric NP, or APRN on site at least five hours/week per 16 clients to assess clients within 24 hours of admission (or earlier, if medically necessary), and available to provide onsite monitoring of care and further evaluation on a daily basis.
 - 16.1.2.3 Primary care/physical health physician (or physician extender) on site at least five hours/week for each 16 clients.
 - 16.1.2.4 One nurse (RN or LPN) per 16 clients on site at all times with an RN supervisor or NP on call.
 - 16.1.2.5 One licensed practitioner or unlicensed counselor with direct supervision on site during days and evenings per 16 clients.
 - 16.1.2.6 One behavioral health technician on site and awake at all times per 15 clients.
 - 16.1.2.7 One full time staff member during clinic hours dedicated to performing referral arrangements for all clients. This staff member may be a licensed practitioner, unlicensed counselor, or certified peer.
- 16.1.3 Meet the following requirements for screening, assessment, and Recovery Planning:
 - 16.1.3.1 Urine drug screens are required upon admission and as directed by the Recovery Plan.
 - 16.1.3.2 A comprehensive nursing assessment at admission, including an addiction-focused history.
 - 16.1.3.3 Assessment of addiction-focused history and ASI shall be reviewed with a physician during the admission process.
 - 16.1.3.4 For individuals new to the program, a comprehensive bio-psychosocial assessment per Title 16 Delaware Administrative Code 6001 shall be completed within 24 hours of admission which substantiates appropriate placement.
 - 16.1.3.5 The assessment shall be reviewed and signed by a qualified professional.
 - 16.1.3.6 Full physical exam within 24 hours.
 - 16.1.3.7 If self-administered withdrawal management medications are to be used, a physical examination by a physician, physician assistant, or nurse practitioner shall be performed at time of admission.
 - 16.1.3.8 Initial individualized, interdisciplinary Recovery Plan, consistent with Title 16 Delaware Administrative Code 6001, completed within 24 hours. This plan should be developed in collaboration with the client.

- 16.1.3.9 A comprehensive Recovery Plan within three days and additional updates to the Recovery Plan as indicated.
- 16.1.3.10 Initial discharge plan within 24 hours of admission, and comprehensive discharge plan prior to discharge.
- 16.1.3.11 Referral and assistance as needed for the client to gain access to other needed SUD or mental health services.
- 16.1.3.12 Implement the Recovery Plan and document the client's response to and/or participation in scheduled activities. Notes shall include:
 - 16.1.3.12.1 The client's physical condition, including vital signs.
 - 16.1.3.12.2 The client's mood and behavior.
 - 16.1.3.12.3 Statements about the client's condition and needs.
 - 16.1.3.12.4 Information about the client's progress or lack of progress in relation to withdrawal management/treatment goals.
 - 16.1.3.12.5 Additional notes shall be documented, as needed.
- 16.1.3.13 Physician orders are required for medical and psychiatric management.

17.0 Medically Monitored Inpatient Withdrawal Management (ASAM Level 3.7-WM)

- 17.1 In addition to the requirements applicable to all programs, an ASAM Level 3.7-WM program shall:
 - 17.1.1 Have Federal Center for Substance Abuse Treatment OTP certification and Drug Enforcement Agency approval
 - 17.1.2 Provide 24-hour observation, monitoring and treatment.
 - 17.1.3 Have an interdisciplinary team of appropriately trained clinicians, such as physicians, nurses, counselors, social workers, and psychologists, available to assess and treat the client and to obtain and interpret information regarding the client's needs. The number and disciplines of team members are appropriate to the range and severity of the client's problems. The interdisciplinary team also includes an array of licensed practitioners, unlicensed counselors, and credentialed behavioral health technicians operating within their scope of practice to provide services appropriate to the bio-psychosocial needs of clients. This includes:
 - 17.1.3.1 A designated medical director available on call at all times. This may be a physician or a provider of addiction pharmacotherapy integrated with psychosocial therapies, including a physician assistant or other independent practitioner with prescribing privileges knowledgeable about addiction treatment.
 - 17.1.3.2 A psychiatrist, psychiatric NP, or APRN on site at least 15 hours/week per 16 clients to assess the client within 24 hours of admission (or earlier, if medically necessary), and available to provide onsite monitoring of care and further evaluation on a daily basis.
 - 17.1.3.3 Primary care/physical health physician (or physician extender) on site at least 15 hours/week for 15 clients.
 - 17.1.3.4 One nurse (RN or LPN) per 16 clients on site at all times with an RN supervisor or NP on call.
 - 17.1.3.5 One licensed practitioner or unlicensed counselor with direct supervision on site during days and evenings per 16 clients.
 - 17.1.3.6 One behavioral health technician on site and awake at all times per 15 clients.
 - 17.1.3.7 One full time staff member dedicated to performing referral arrangements for all clients served by the facility. This staff member may be a licensed practitioner, unlicensed counselor, or certified peer.
 - 17.1.4 Meet the following requirements for screening, assessment, and Recovery Planning:
 - 17.1.4.1 Urine drug screens are required upon admission and as directed by the Recovery Plan.
 - 17.1.4.2 A comprehensive nursing assessment at admission, including an addiction-focused history.
 - 17.1.4.3 Assessment of addiction-focused history and ASI to be reviewed with a physician during the admission process.
 - 17.1.4.4 For individuals new to the program, a comprehensive bio-psychosocial assessment per Title 16 Delaware Administrative Code 6001 shall be completed within 24 hours of admission which substantiates appropriate patient placement. This assessment must be reviewed and signed by a qualified professional.
 - 17.1.4.5 Full physical exam within 24 hours.

- 17.1.4.6 If self-administered withdrawal management medications are to be used, a physical examination by a physician, physician assistant, or NP shall be completed at time of admission.
- 17.1.4.7 Initial individualized, interdisciplinary Recovery Plan, consistent with Title 16 Delaware Administrative Code 6001 shall be completed within 24 hours of admission. This plan should be developed in collaboration with the individual.
- 17.1.4.8 A comprehensive Recovery Plan shall be completed within three days of admission and additional updates to the Recovery Plan as indicated.
- 17.1.4.9 Initial discharge plan within 24 hours of admission, and comprehensive discharge plan at discharge.
- 17.1.4.10 Referral and assistance as needed for the client to gain access to other needed SUD or mental health services.
- 17.1.4.11 Implement the Recovery Plan and document the client's response to and/or participation in scheduled activities. Notes shall include:
 - 17.1.4.11.1 The client's physical condition, including vital signs.
 - 17.1.4.11.2 The client's mood and behavior.
 - 17.1.4.11.3 Statements about the client's condition and needs.
 - 17.1.4.11.4 Information about the client's progress or lack of progress in relation to withdrawal management/treatment goals.
 - 17.1.4.11.5 Additional notes shall be documented, as needed.
- 17.1.4.12 Physician orders are required for medical and psychiatric management.

18.0 Clinically Managed Low Intensity Residential Treatment (ASAM Level 3.1)

- 18.1 In addition to the requirements applicable to all programs, an ASAM Level 3.1 program shall:
 - 18.1.1 Offer at least 10 hours per week of a combination of low-intensity clinical and recovery-focused services, including:
 - 18.1.1.1 At least five hours a week shall include individual, group, family therapy, medication management, and psycho-education.
 - 18.1.2 Provide treatment directed toward applying recovery skills, preventing relapse, improving emotional functioning, promoting personal responsibility, and reintegrating the individual into the worlds of work, education, and family life.
 - 18.1.2.1 Mutual/self-help meetings usually are available on site.
 - 18.1.3 Provide an array of licensed practitioners, unlicensed counselors and credentialed behavioral health technicians operating within their scope of practice to provide services appropriate to the biopsychosocial needs of individuals. This includes:
 - 18.1.3.1 Although they do not provide direct services, a physician is part of the interdisciplinary team either through employment or contractual arrangement. The physician shall be available at least two and one-half hours per week to review admission decisions and confirm medical necessity of services.
 - 18.1.3.2 One licensed practitioner or unlicensed counselor with direct supervision per 16 residents on site during the day. A licensed practitioner/unlicensed counselor shall be on call 24/7 when not on site.
 - 18.1.3.3 Caseload size is based on needs of individuals actively engaged in services to ensure effective, individualized treatment, and rehabilitation but should not exceed 35 active individuals for each licensed practitioner and unlicensed counselor. For this standard, active is defined as being treated at least every 90 days.
 - 18.1.3.4 House manager (1 full time staff member per shift) awake and on site at night to supervise activities of the facility and shall have adequate orientation and skills to assess situations related to relapse and to provide access to appropriate medical care when needed.

19.0 Clinically Managed Population-Specific High Intensity Residential Treatment (ASAM Level 3.3) and Clinically Managed High Intensity Residential Treatment (ASAM Level 3.5)

- 19.1 In addition to the requirements applicable to all programs, an ASAM Level 3.3 or an ASAM Level 3.5 program shall:
 - 19.1.1 Offer 24-hour treatment staff with at least 30 hours per week of a combination of clinical and recovery-focused services including:
 - 19.1.1.1 At least 10 hours shall include individual, group, and/or family counseling.
 - 19.1.2 Be characterized by their reliance on the treatment community as a therapeutic agent.

- 19.1.3 Provide an array of licensed practitioners, unlicensed counselors and credentialed behavioral health technicians operating within their scope of practice to provide services appropriate to the biopsychosocial needs of individuals admitted to the program. These programs shall have medical personnel including physicians or physician extenders knowledgeable about addiction treatment, appropriately credentialed licensed mental health professionals, and allied health professional staff. The number and disciplines of team members are appropriate to the range and severity of the individual's problems. This includes:
- 19.1.3.1 A designated medical director available on call at all times. This may be a physician or psychiatrist or a provider of addiction pharmacotherapy integrated with psychosocial therapies including a physician assistant or other independent practitioner with prescribing privileges knowledgeable about addiction treatment.
 - 19.1.3.2 An RN on site. The number of hours provided is to be determined by the needs of the individuals served.
 - 19.1.3.3 A psychiatrist, psychiatric NP or PA on site. The number of hours provided is to be determined by the needs of the individuals served.
 - 19.1.3.4 A primary care/physical health physician (or physician extender) on site. The number of hours provided is to be determined by the needs of the individuals served.
 - 19.1.3.5 One licensed practitioner or unlicensed counselor with direct supervision per 16 clients on site during days and evenings and on call 24/7 when not on site.
 - 19.1.3.6 One behavioral health technician per 16 clients on site and awake at all times.
- 19.1.4 Meet the following requirements for screening, assessment, and Recovery Planning:
- 19.1.4.1 A urine drug screen and a tuberculosis test are required within 72 hours of admission and as directed by the Recovery Plan.
 - 19.1.4.2 Nursing assessment within 24 hours of admission that is reviewed by a physician to determine need for eligibility and appropriateness for admission and referral.
 - 19.1.4.3 For individuals new to the program, a comprehensive bio-psychosocial assessment per Title 16 Delaware Administrative Code 6001 shall be completed within 48 hours of admission which substantiates appropriate patient placement. This assessment must be reviewed and signed by a qualified professional.
 - 19.1.4.4 A physical examination performed by QMP within seventy-two (72) hours of admission unless the client presents a copy of a physical examination completed by qualified medical personnel within ninety (90) days prior to admission.
 - 19.1.4.5 Individualized, interdisciplinary Recovery Plan, consistent with Title 16 Delaware Administrative Code 6001 shall be developed within 72 hours of admission and in collaboration with the client.
 - 19.1.4.6 The Recovery Plan shall be reviewed in collaboration with the client every 30 days and documented accordingly.
 - 19.1.4.7 Discharge/transfer planning shall begin at admission.
 - 19.1.4.8 Referral and assistance shall be provided as needed for the client to gain access to other needed SUD or mental health services.

20.0 Medically Monitored Intensive Inpatient Treatment (ASAM Level 3.7)

- 20.1 In addition to the requirements applicable to all programs, an ASAM Level 3.7 program shall:
- 20.1.1 Provide thirty (30) hours of structured treatment activities per week including, but not limited to psychiatric and substance use assessments, diagnosis treatment, and rehabilitation services, including:
 - 20.1.1.1 At least ten (10) of the thirty (30) hours includes individual, group, and/or family counseling
 - 20.1.2 Provide a planned regimen of 24-hour professionally directed evaluation, observation, and medical monitoring of addiction and mental health treatment in an inpatient setting.
 - 20.1.3 Provide an array of licensed practitioners, unlicensed counselors and credentialed behavioral health technicians operating within their scope of practice to provide services appropriate to the biopsychosocial needs of clients. ASAM Level 3.7 programs shall have medical personnel, including physicians or physician extenders, knowledgeable about addiction treatment, appropriately credentialed licensed mental health professionals, and allied health professional staff. The number and disciplines of team members are appropriate to the range and severity of the individual's problems. This includes:
 - 20.1.3.1 A designated medical director or a psychiatrist available on call at all times. This may be a physician or psychiatrist or a provider of addiction pharmacotherapy integrated with psychosocial therapies including a physician assistant or other independent practitioner with prescribing privileges knowledgeable about addiction treatment.

- 20.1.3.2 A psychiatrist or psychiatric NP on site at least 10 hours/week for every 16 clients.
- 20.1.3.3 A primary care/physical health physician (or physician extender) on site at least five hours/week for every 16 clients.
- 20.1.3.4 One RN on day shift per 16 clients to oversee and monitor client progress and medication administration. One LPN at all times per 16 clients.
- 20.1.3.5 One licensed or certified clinician or counselor with direct supervision on site during days and evenings for every 16 clients.
- 20.1.3.6 One behavioral health technician on site and awake at all times for every 16 clients.
- 20.1.4 Meet the following requirements for screening, assessment, and Recovery Planning:
 - 20.1.4.1 A urine drug screen and a tuberculosis test are required within 72 hours of admission and as directed by the Recovery Plan.
 - 20.1.4.2 A comprehensive nursing assessment at admission.
 - 20.1.4.3 For individuals new to the program, a comprehensive bio-psychosocial assessment per Title 16 Delaware Administrative Code 6001 completed within 24 hours of admission which substantiates appropriate placement. This assessment must be reviewed and signed by a qualified professional.
 - 20.1.4.4 A physical examination performed by a physician within 24 hours of admission, or a review and update by the facility physician of the record of a prior physical exam completed no more than seven days prior to admission.
 - 20.1.4.5 Individualized, interdisciplinary Recovery Plan, consistent with Title 16 Delaware Administrative Code 6001, completed within 72 hours of admission. This plan should be developed in collaboration with the individual.
 - 20.1.4.6 The Recovery Plan shall be reviewed and updated in collaboration with the client every 30 days and documented accordingly.
 - 20.1.4.7 Discharge/transfer planning shall begin at admission.
 - 20.1.4.8 Referral and assistance shall be provided as needed for the client to gain access to other.

14 DE Reg. 471 (11/01/10)

18 DE Reg. 938 (06/01/15) (Prop.)