



*Delaware Health
And Social Services*

DIVISION OF MANAGEMENT SERVICES

PROCUREMENT

DATE August 12, 2014

HSS 14 027
Comprehensive Behavioral Health Outpatient Treatment Services for Adults
FOR
DIVISION SUBSTANCE ABUSE AND MENTAL HEALTH

Date Due: September 5, 2014
11:00AM

ADDENDUM # 2

Please Note:

THE ATTACHED SHEETS HEREBY BECOME A PART OF
THE ABOVE MENTIONED BID. Draft Licensure Regulations

Kieran Mohammed
PROCUREMENT ADMINISTRATOR
(302)255-9291

Cesar McClain
(302) 255-9417

STATE OF DELAWARE

TABLE OF CONTENTS

PART I: LICENSURE

SECTION 1.0	PURPOSE	3
SECTION 2.0	STATUTORY AUTHORITY AND APPLICABILITY.....	3
SECTION 3.0	DEFINITIONS	3
SECTION 4.0	LICENSING PROCESS AND PROCEDURES	10

PART II: AGENCY GOVERNANCE AND COMPLIANCE

SECTION 5.0	GOVERNING BODY	17
SECTION 6.0	CORPORATE COMPLIANCE AND ETHICS.....	19
SECTION 7.0	FISCAL OVERSIGHT	21
SECTION 8.0	PROFESSIONAL SERVICES OVERSIGHT	22
SECTION 9.0	POLICIES AND PROCEDURES	22
SECTION 10.0	RESEARCH	23

PART III: FACILITY AND PROGRAM MANAGEMENT

SECTION 11.0	MANAGEMENT STRUCTURE AND ACCOUNTABILITY	24
SECTION 12.0	HUMAN RESOURCES	25
SECTION 13.0	INFORMATION MANAGEMENT	28
SECTION 14.0	CLIENT RECORDS.....	29
SECTION 15.0	ENVIRONMENT OF CARE	29
SECTION 16.0	PERFORMANCE IMPROVEMENT.....	32

PART IV: CLIENTS' RIGHTS AND PROTECTIONS

SECTION 17.0	RIGHTS OF CLIENTS IN ALL PROGRAMS AND SERVICES.....	34
SECTION 18.0	RIGHTS OF CLIENTS IN RESIDENTIAL AND INPATIENT PROGRAMS.....	37
SECTION 19.0	CONFIDENTIALITY	40
SECTION 20.0	CONCERN AND COMPLAINT RESOLUTION	41

PART V: GENERAL STANDARDS OF PROFESSIONAL CARE APPLICABLE TO ALL PROGRAMS AND SERVICES

SECTION 21.0	CLIENT INTAKE SCREENING.....	42
SECTION 22.0	DIAGNOSTIC ASSESSMENT.....	44
SECTION 23.0	TREATMENT APPROACH.....	46
SECTION 24.0	RECOVERY PLANNING AND DOCUMENTATION	47
SECTION 25.0	PROGRESS NOTES.....	49
SECTION 26.0	DISCHARGE SUMMARY AND CONTINUING CARE.....	50
SECTION 27.0	PHARMACEUTICAL SERVICES – ALL FACILITIES WHICH DISPENSE OR ADMINISTER MEDICATIONS	52
SECTION 28.0	PHARMACEUTICAL SERVICES – ALL FACILITIES WHICH DO NOT DISPENSE OR ADMINISTER MEDICATIONS	55
SECTION 29.0	TOBACCO CESSATION	56
SECTION 30.0	USE OF PEER RECOVERY SUPPORTS	57

PART VI: STANDARDS APPLICABLE TO CATEGORIES OF PROGRAMS

SECTION 31.0	STANDARDS APPLICABLE TO ALL RESIDENTIAL AND INPATIENT PROGRAMS	57
SECTION 32.0	STANDARDS APPLICABLE TO ALL OPIOID TREATMENT PROGRAMS	59
SECTION 33.0	STANDARDS APPLICABLE TO ALL CO-OCCURRING PROGRAMS/SERVICES	64

PART VII: STANDARDS APPLICABLE TO SPECIFIC PROGRAMS AND SERVICES

<u>SECTION 34.0</u>	<u>CLINIC-BASED ASSESSMENTS AND CASE MANAGEMENT SERVICES.....</u>	<u>64</u>
<u>SECTION 35.0</u>	<u>CRISIS INTERVENTION.....</u>	<u>66</u>
<u>SECTION 36.0</u>	<u>23-HR PSYCHIATRIC CRISIS OBSERVATION, EVALUATION AND STABILIZATION SERVICES</u>	<u>67</u>
<u>SECTION 37.0</u>	<u>23-HR SUBSTANCE-RELATED OBSERVATION, EVALUATION AND REFERRAL SERVICES</u>	<u>68</u>
<u>SECTION 38.0</u>	<u>OUTPATIENT TREATMENT SERVICES</u>	<u>70</u>
<u>SECTION 39.0</u>	<u>INTENSIVE OUTPATIENT TREATMENT PROGRAMS.....</u>	<u>72</u>
<u>SECTION 40.0</u>	<u>AMBULATORY WITHDRAWAL MANAGEMENT SERVICES.....</u>	<u>74</u>
<u>SECTION 41.0</u>	<u>OUTPATIENT OPIOID TREATMENT PROGRAMS.....</u>	<u>78</u>
<u>SECTION 42.0</u>	<u>CLINICALLY MANAGED LOW-INTENSITY RESIDENTIAL SERVICES</u>	<u>83</u>
<u>SECTION 43.0</u>	<u>CLINICALLY MANAGED HIGH-INTENSITY RESIDENTIAL PROGRAMS</u>	<u>86</u>
<u>SECTION 44.0</u>	<u>CLINICALLY MANAGED RESIDENTIAL WITHDRAWAL MANAGEMENT.....</u>	<u>89</u>
<u>SECTION 45.0</u>	<u>MEDICALLY MONITORED INPATIENT WITHDRAWAL MANAGEMENT.....</u>	<u>91</u>

DRAFT

Part I: Licensure Provisions

Section 1.0 Purpose

- 1.1 The Department is issuing these regulations (that are revised as necessary) to promote the health and well-being of clients receiving services in substance use, mental health, and co-occurring disorders treatment programs and facilities located within the state of Delaware. They are not intended to limit additional contract requirements for such facilities and programs with which a service provider may be expected to comply.
- 1.1.1 The Division shall review, revise and, when necessary, amend these regulations no less frequently than every three (3) years.

Section 2.0 Statutory Authority and Applicability

- 2.1 The Department is authorized by 16 Del.C. Ch. 22 to license and regulate substance use, mental disorder, and co-occurring mental disorder treatment facilities. These regulations shall apply to any facility as defined in 16 Del.C. Chs. 22 and 51 and address the minimum acceptable standards and programmatic conditions for clients receiving services in behavioral health disorders treatment facilities. No organization or entity shall manage or operate such a treatment 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 services to individuals in Delaware in need of programs and services for substance use and/or mental disorders in outpatient, residential and inpatient settings when they provide any such services covered under these regulations.
- 2.2.1 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.
- 2.2.2 These regulations shall not apply to: independent practitioner or group practice office-based services, hospitals, urgent medical care centers, State hospitals, or private psychiatric hospitals.

Section 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.
- “45 CFR Parts 160 and 164” refers to parts 160 and 164 of Title 45 of the U.S. Code of Federal Regulations referring to the confidentiality protections of the personal health information of individuals receiving health services in the United States. This Title is commonly referred to as ‘HIPAA’.
- “Acceptable compliance” means the demonstration of an agency or licensee to adequately meet all licensing standards considered by the Division to be essential, and to sufficiently meet all other standards in these regulations, with or without a corrective action plan, as determined by the Division’s Quality Assurance Unit and authorized by the Director.
- “Addictive Disorder” A new DSM-5 category of disorders in which the sole condition is currently gambling disorder and which will include any conditions covered in this category in any

revised editions.

“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 (e.g., president, chief executive officer, executive director).

“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 agency board to act in lieu of the governing body, typically in organizations that are for-profit or national organizations based in another state.

“Agency” means any partnership, corporation, association, or other legal entity, except for an individual practitioner, that provides, is seeking to provide, or holds itself out as providing substance use, addictive disorder, mental disorder, or co-occurring disorder 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, addictive disorder, mental disorder, 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](#).

“Aversive Techniques” are those requiring the deliberate application of discomforting, painful or noxious stimuli (that would be so to the average person) to achieve their effectiveness. **These techniques are prohibited in Delaware.**

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

“Behavioral Management” means any intervention or treatment that utilizes positive reinforcers and/or restrictions to help an individual receiving services to develop and/or strengthen recovery-oriented behaviors and to address and correct treatment targeted behaviors.

“Biologicals” means medicinal preparations made from living organisms and their products, including serums, vaccines, antigens, antitoxins, etc.

Caseload equivalent” means a metric that assigns weights to the number of clients on a caseload based on the planned frequency of their participation in treatment to determine what constitutes a maximum caseload. For example, the metric accounts for the fact that clients in their initial phase of treatment may be seen with more frequency than a client being seen for continuing care or ongoing disease management. The participating client equivalents are determined in the following manner: A client seen once per week would count as 1.0 client equivalent; a client seen bi-weekly would count as a .5 client equivalent; a client seen monthly or less would count as a .25 client equivalent. As an example, a counselor has 15 clients that are seen weekly (counts as 15 equivalent clients), 30 clients seen biweekly (counts as 15 equivalent clients), and 8 clients seen monthly (counts as 2 equivalent clients). The counselor would have a total caseload of 53 individual clients equaling 32 equivalent clients.

“CFR” means the Code of Federal Regulations of the United States.

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

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

"Collateral" means any individual who collaborates with or supports a client, typically outside the immediate family (e.g., personal physician, recovery coach, probation officer, etc.).

"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.

"Co-occurring Disorder" in these regulations means substance use, addictive disorders, and mental disorders that co-exist; a term interchangeable with "dual diagnosis".

"Co-occurring Capable" means a the ability of a program to deliver comprehensive services to clients with a substance use disorder or a mental disorder and has the ability to also address the other disorder to a degree that meets dual diagnosis capable (DDC) criteria as measured using either the DDCAT or DDCMHT instruments.

"Co-occurring Enhanced" means a the ability of a program to deliver equally comprehensive services to clients with both a substance use and a mental disorder preferably in an integrated manner, and to a degree that meets dual diagnosis enhanced (DDE) criteria as measured using either the DDCAT or DDCMHT instruments.

"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 I or Counselor II and two or more clients or clients' families/significant others for a specific therapeutic purpose.

"Cultural Competence" means capacity of a service provider or organization to understand and work effectively in accord with the beliefs and practices of persons from a given ethnic/racial/religious/social group or sexual orientation. It includes the holding of knowledge, skills, and attitudes that allow the treatment provider and program to understand the full context of a patient's current and past socio-environmental situation.

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

"DDCAT" means the Dual Diagnosis Capability in Addictions Treatment, an instrument developed by Dartmouth University to assess the capability of a primary substance use disorder program to meet the needs of individuals with co-occurring mental disorders.

"DDCMHT" means the Dual Diagnosis Capability in Mental Health Treatment, an instrument developed by Dartmouth University to assess the capability of a primary mental disorder program to meet the needs of individuals with co-occurring substance use disorders.

"Del.C." means the Delaware Administrative Code.

"Department or DHSS" means the State of Delaware Department of Health and Social Services.

"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 or DSAMH" means the Division of Substance Abuse and Mental Health within the

Delaware Department of Health and Social Services.

“**Director**” means the Director of the 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 (including electronic version) acceptable as evidence to substantiate compliance with these regulations.

“**DSM-5**” means the *Diagnostic and Statistical Manual of Mental Disorders*, most recent edition (i.e., version five), as published by the American Psychiatric Association (2013).

“**EMDR**” stands for Eye Movement Desensitization and Reprocessing, an integrative psychotherapy approach that has been extensively researched and proven effective for the treatment of trauma.

“**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).

“**Exceptional compliance**” means the demonstration of an agency or licensee to fully meet all licensing standards considered by the Division to be essential, and to a largely meet all other standards in these regulations, without a corrective action plan, as determined by the Division’s Quality Assurance Unit and authorized by the Director.

“**Facility**” means the physical area, grounds, building(s) or portions thereof, under direct program and/or sponsoring agency’s administrative control.

“**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.

“**Governing Body**” means the individual or individuals legally responsible for the overall operation of an agency, and for ensuring compliance with these regulations.

“**HIPAA**” means the Health Insurance Portability and Accountability Act of 1996, used herein generally to refer to the privacy and confidentiality provisions of the Act (45 CFR Parts 160 and 164).

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

“**Initial Recovery Plan**” means a preliminary recovery plan developed within the early hours or days of treatment (or when the client is medically stable) and that is completed over time according to the timeframes established in each level of care. 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 an individual should be admitted to a program.

“**Intern**” means a student who performs counseling functions under the supervision of a clinical supervisor as authorized by agency policy.

“**License**” means the document issued by the Division that authorizes a program to provide behavioral health disorder treatment and/or rehabilitation under these regulations.

“**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. A LBHP includes professionals licensed to practice independently:

- Licensed psychologists.
- Licensed clinical social workers (LCSWs).
- Licensed professional counselors of mental health (LPCMHS).
- Licensed marriage and family therapists (LMFTs).

“Licensed Nurse” means a Registered Nurse (RN) or a Licensed Practical Nurse (LPN).

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

“Licensee” means an agency that currently holds a valid license under these regulations.

“Licensure” means the process by which the Division determines whether or not a program is in sufficient compliance with these regulations to warrant issuance of a license.

“Medical Doctor” means a physician licensed to practice medicine (e.g., M.D. or Doctor of Osteopathy [D.O.]

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

“Medically Supervised Withdrawal” means dispensing of an opioid medication 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” 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. Medication assisted treatment (MAT) is clinically driven with a focus on individualized patient care. MAT for opioid disorders includes a medication (e.g., methadone, buprenorphine, naltrexone) approved by the U.S. Food and Drug Administration (FDA) for opioid medically supervised withdrawal management or maintenance treatment.

“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 populations 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).

“OTP” means an Opioid Treatment Program that is federally certified by 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 SOTA.

“Peer Recovery Specialists” means a consumer who, through training and experience, works to support peers who need the support. A peer recovery specialist is in the process of recovering from a mental illness and/or addiction. Peer Recovery specialists can run support groups, participate in training opportunities for other consumers, and participate on treatment teams to advocate for resources needed by consumers. A peer specialist shares their lived experience as a way of helping other consumers. Peer specialists will be hired by the Delaware Psychiatric Center in the capacities of peer support specialist and bridge peer specialist. A bridge peer specialist helps consumers as they transition from one level of care to another. All peer specialists will have training in facilitating support groups.

“Performance Improvement” 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.

“Periodic recovery plan review/revision” is a process whereby the clinical supervisor and counselor review prior recovery plans and establish current goals based on the client’s progress and/or changing needs throughout a course of 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 (i.e., PA).

“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 a generalized term for an organized system of services designed to address the behavioral health needs of clients. 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.

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

“Program Physician” means a physician either employed by, or under written contract with, an agency providing direct medical services to clients at a program.

“Progress notes” means permanent 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.

“PROMISE” means PRomoting Optimal Mental Health for Individuals through Supports and Empowerment

“Protocol” means a written rule developed by an agency to govern specific procedures or certain activities.

“Provisional license” means the document issued by the Division that authorizes a program to provide substance use, addictive disorder, mental disorder, and/or co-occurring disorder 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.

“Psychiatrist” means a medical doctor who is State Board certified to practice psychiatry in the State of Delaware.

“Public place” means an area accessible to clients, employees or visitors (e.g., 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” QPP means a physician or nurse practitioner, licensed by the State of Delaware with specific clinical experience in the treatment of substance use and addictive disorders and mental disorders. Qualified Psychiatric Practitioners must have specific training in the use of opioid agonist medications, as well as the use of psychotropic medications with individuals who have a mental disorder diagnosis.

“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.

“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 Coach” means a non-clinician who uses a supportive, collaborative, and strengths-based approach to help individuals achieve sustained recovery from addiction and gain access to needed community resources by assisting them in overcoming barriers and helping them bridge gaps between their needs and available resources. *See Peer Recovery Specialist*.

“Registered Nurse” means a person licensed by the State of Delaware as a registered nurse (i.e., RN) or a person licensed by a State that participates in the National Licensure Compact (NLC).

“Representative Payee” means a person who acts as the receiver of United States Social Security Disability or Supplemental Security Income for a person who is not fully capable of managing their own benefits and finances.

“SAMHSA” means the Substance Abuse and Mental Health Services Administration of the U.S. Department of Health and Human Services.

“Secretary” means the cabinet Secretary of the Delaware Department of Health and Human Services, appointed by the Governor.

“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 date when required.

“Significant Other” means an individual, whether or not related by blood or marriage, on which another individual willfully relies for support.

“SOTA” means the State Opioid Treatment Authority, designated by the Director to oversee regulation of OTPs operating in Delaware.

“Staff” means full-and part-time employees, consultants, volunteers, and students/interns who are affiliated through written agreement and work at a program.

“Stages of Change” means a model developed to gauge a client’s readiness and preparedness to make life changes including both cognitive and behavioral. It includes five major stages: pre-contemplation, contemplation, preparation, action, and maintenance.

“Stages of Treatment” means a step-wise progression a client experiences that provides benchmarks of progress, generally including at least: engagement, persuasion, active treatment, and relapse prevention.

“Substance” means alcohol, nicotine, other drugs (including both illicit or licit) and medications or compounds or materials having chemical properties that, after entering a human body affect the person in a manner that especially alters mood and/or perception, and particularly including those that have potential to contribute to the development of a substance use disorder.

“Substance Use Disorder” means a maladaptive pattern of substance use leading to clinically significant impairment or distress, as manifested by 2 (or more) DSM-5 specified conditions occurring within a 12-month period.

“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.

“Telemedicine” means consultations, office visits, individual psychotherapy, and pharmacological management services provided via telecommunication technology.

“Unlicensed counselors and assessors” include 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), and licensed chemical dependency professional (LCDP) under the supervision of a licensed professional.

“Volunteer” means a person who, without direct financial compensation, provides services or other assistance to a behavioral health program or service.

“Waiver” means an exemption from compliance with a specific requirement of these regulations as authorized by the Director.

“Withdrawal management” means a set of interventions aimed at managing acute intoxication and withdrawal. It is often the first step taken by persons with a SUD 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.

Section 4.0 Licensing Procedures

4.1 Applicability

4.1.1 Any agency seeking to operate a behavioral health service or program(listed

below) shall obtain a license for each service or program it seeks to operate. Each license shall list one or more categories of service that the agency is authorized to provide and the location(s). The Division may also specify the approved static client capacity of a licensed service or program.

4.2 Licensing Categories

Program and service categories for which licenses may be issued are:

- 4.2.1 Clinic-Based Assessment and Conflict-Free Case Management Services (PROMISE)
- 4.2.2 23-Hour Substance-Related Observation, Evaluation and Referral Services
- 4.2.3 23-Hour Crisis Observation, Evaluation and Stabilization Services
- 4.2.4 Outpatient Treatment Services
- 4.2.5 Intensive Outpatient Treatment Programs
- 4.2.6 Withdrawal Management Services
- 4.2.7 Outpatient Opioid Treatment Programs
- 4.2.8 Clinically Managed Low Intensity Residential Treatment
- 4.2.9 Clinically Managed High Intensity Residential Treatment
- 4.2.10 Clinically Managed Residential Withdrawal Management
- 4.2.11 Medically Monitored Inpatient Withdrawal Management

4.3 Application Procedures

- 4.3.1 The Division may supply an application packet to applicants upon request. Applications can also be obtained by the applicant from the Division's website.
- 4.3.2 All agencies applying for a license for the first time or for any new or additional program site shall meet with DSAMH Quality Assurance division staff for the purpose of receiving needed 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 behavioral health disorder program.
- 4.3.4 The applicant may withdraw the application at any time by notifying the Division in writing.

4.4 Required Information

An applicant for licensure shall submit the following information on forms provided by the Division:

- 4.4.1 Name and address of the applicant, including identification of corporate ownership, and IRS status of the agency and parent entity if different;
- 4.4.2 Name, address and qualifications of the agency administrator, program director and/or partners, including copies of the active professional licenses each has been issued by the State of Delaware and/or another State;
- 4.4.3 Articles of incorporation and bylaws, and/or partnership agreement of the agency and any parent corporation(s) or entity;
- 4.4.4 Name and address, occupation and place of employment, of the agency and parent organization board members, advisory board members, and officers;

- 4.4.5 Organization charts of both the agency and programs showing incumbent names, positions, degrees and credentials (e.g., license, certification); all vacant positions; and illustrating direct and indirect reporting and supervisory relationships;
- 4.4.6 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;
- 4.4.7 A copy of the program's complete proposed policies and procedures manual if the application is for initial licensure; and a current revised version for renewal applications;
- 4.4.8 Documentation of all insurance coverage required in these regulations;
- 4.4.9 A floor plan for any facility not previously licensed;
- 4.4.10 For residential and withdrawal management facilities, the maximum client capacity requested; and
- 4.4.11 A copy of the agency's Delaware business license and home state license, when applicable.
- 4.4.12 Applicants shall supply all information requested in the application. The completed application shall be accompanied by a 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.

4.5 Application Processing

- 4.5.1 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.
- 4.5.2 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.
- 4.5.3 Programs cannot begin providing services under these standards until an official letter or license is issued by the Division.

4.6 Investigations and Inspections

- 4.6.1 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.
- 4.6.2 Applicants applying for licensure shall have the following information available for inspection by the Division:
 - 4.6.2.1 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 program, service, and/or facility being licensed;
 - 4.6.2.2 A copy of the agency and program's policies and procedures as required in these regulations;

- 4.6.2.3 Materials demonstrating compliance with all other relevant sections of these regulations; and
- 4.6.2.4 Active and closed clinical records for sample review or a sample record for new programs.
- 4.6.3 Investigations and inspections may include unannounced on-site inspections of the program and its operation; inspection and copying (in accordance with 42 CFR Part 2, and 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 person who may have information bearing on the applicant's or licensee's compliance or ability to comply with these regulations.

4.7 Division Report

- 4.7.1 Upon completion of any inspection or investigation, the Division shall compile a Survey Summary Report citing strengths and recommendations for addressing deficiencies in meeting these standards.
- 4.7.2 The Division shall conduct an exit interview with each program for review of the Survey Summary Report.

4.8 Corrective Action Plans

- 4.8.1 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.
- 4.8.2 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.
- 4.8.3 The Division may perform follow-up on-site inspections (including unannounced visits) to review the implementation of Corrective Action Plan(s).
- 4.8.4 The Division shall notify the agency in writing when it determines the action steps in the Corrective Action Plan to have been successfully addressed.

4.9 Actions on Applications for Licensure

- 4.9.1 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:
 - 4.9.1.1 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 16 Del.C. Ch. 22, and these regulations;
 - 4.9.1.2 Renew a full license for a period of up to two (2) years at the sole discretion of the Director when the Division determines that a program has been in *exceptional compliance* with 16 Del.C. Ch. 22 and these regulations for at least three (3) consecutive years;
 - 4.9.1.3 Issue a provisional license for up to one hundred and eighty (180) days when the program is not in compliance with 16 Del.C.

Ch.22, and the applicant's failure to meet the requirements of 16 Del.C. Ch. 22, and these regulations, does not jeopardize the health, safety and well-being of clients. The Division may issue one (1) 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);

4.9.1.4 Issue an extension of the current 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 16 Del.C. Chs. 22 and 51, 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 an extension of the license instead of a full or provisional license is final and not subject to administrative appeal); or

4.9.1.5 Revoke, suspend or deny a license in accordance with these regulations.

4.9.2 The Division shall notify the program in writing by mail and/or email of its licensure decision.

4.10 Access by the Division

4.10.1 An agency's programs, services, and facilities are subject to review, which may include on-site inspection, with or without notice, by the Division. The Division's right to monitor shall include complete access to all clients, staff, board members, and financial and administrative program records needed for the purposes of monitoring or evaluation of compliance with these regulations, financial auditing, or for research. The Division may review and copy records in accordance with 42 CFR Part 2, and 45 CFR Parts 160 and 164.

4.11 Non-Assignability; Change in Circumstances; Posting

4.11.1 A license for the operation of a program or service under these regulations applies to the program and/or service and the premises in which the program or service operates.

4.11.2 Licenses are not transferable, remain the property of the Division, and shall be returned upon request.

4.11.3 The current license of a program or service shall be posted at its facility in a public place in plain view of any visitors (e.g., front lobby).

4.11.4 The Division issues each license on the basis of information available to it up to the date the license is issued. Any licensee shall give written notice to the Division of any proposed change of program or service name, ownership, governing entity, premises, or location, a minimum of thirty (30) days before such change takes effect. The Division shall notify the licensee in writing within fifteen (15) days of the receipt of such notice whether a new application is required.

4.11.5 Any person or entity acquiring ownership of a program and/or agency licensed under these regulations shall apply for a new license in

accordance with these regulations.

4.11.6 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 regulations concerning the retention and disposition of clinical records.

4.11.7 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 and to ensure a responsible transition.

4.11.8 In the event of an emergency that requires relocation or closure of a program, the licensee shall immediately notify the Division Director by any means and cooperate fully with the Division to facilitate transfer of clients, as necessary, and to acquire temporary and/or permanent facility/ies for relocation.

4.12 Relationship to Funding

4.12.1 The issuance of a license to a program is not a commitment by the Division to fund, or purchase services from, the agency/program.

4.13 Reasons for Denial, Suspension or Revocation of License

4.13.1 A license may be denied, suspended or revoked for any of the following reasons:

4.13.1.1 When a licensee or applicant submits false information to the Division for licensing purposes;

4.13.1.2 When a licensee or applicant fails to cooperate with the Division in connection with a licensing inspection or investigation, including denying access to the facility at any time;

4.13.1.3 When a licensee or applicant has deviated from the category of service listed on its license;

4.13.1.4 When a licensee or applicant fails to be in compliance with the requirements of these regulations for the types of services for which the application was made or for which the program was licensed;

4.13.1.5 When an licensee fails to implement a Corrective Action Plan it submitted pursuant to these regulations within the approved timeframe, unless the Division approves an extension or modification of the Corrective Action Plan;

4.13.1.6 When a licensee or applicant has egregiously and/or intentionally violated any substantive part of these regulations;

4.13.1.7 When a licensee or applicant has a history of, or currently demonstrates, significant financial instability, or insolvency, such as:

4.13.1.7.1 Filing for bankruptcy;

4.13.1.7.2 Being subjected to foreclosure, eviction for failure to pay rent, or termination of utility services for failure to pay bills; or

4.13.1.7.3 Failing to pay such taxes as FICA, unemployment or Social Security in a

timely manner:

- 4.13.1.8 When the licensee or applicant is in violation of a serious safety or sanitation statute, regulation or ordinance, and fails to correct the violation within a reasonable timeframe;
- 4.13.1.9 When the licensee or applicant, its governing body or owner participates in, condones, or is associated with fraud, deceit, coercion, misrepresentation or other such illegal act;
- 4.13.1.10 When the licensee or applicant, or any of its personnel or governing body violate professional ethics;
- 4.13.1.11 When the licensee or applicant, or any of its personnel or governing body, permits, aids or abets the commission of an unlawful act within its programs or facilities or permits, aids or abets the commission of an unlawful act involving alcohol and/or other drugs within the agency or program; or
- 4.13.1.12 When the licensee or applicant, 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, health, or well-being of any client.

4.14 Procedure when a License is Denied, Suspended or Revoked

- 4.14.1 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 or service was licensed; or has committed an act or engaged in conduct or practices justifying denial, suspension, or revocation of licensure, then, the Division shall issue a *Notice of Intended Action* to 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.
- 4.14.2 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.
- 4.14.3 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, regulations and rules involved; and a short and plain statement of the matters asserted.
- 4.14.4 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 *subpoena duces tecum*, which shall be served and returned as provided by law.

- 4.14.5 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.
- 4.14.6 All hearings shall be open to the public and a full record and transcript of the proceedings shall be prepared. The Secretary shall make a determination, which shall specify the Department's findings of fact and conclusions. A copy of the written determination shall be sent by certified mail, return receipt requested, or be personally served upon the applicant or licensee.
- 4.14.7 Copies of the transcription may be obtained by any interested party upon payment of the cost of preparing such copies.

4.15 Procedure for Reinstatement of Suspended or Revoked License

- 4.15.1 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.
- 4.15.2 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 (1) year after the suspension or revocation determination becomes final.
- 4.15.3 The request for a hearing shall be in writing and shall be delivered to the Secretary in person or by certified mail, return receipt requested.
- 4.15.4 Any hearing conducted under this subsection shall not operate to stay or supersede any decision revoking or suspending a license.
- 4.15.5 Hearings under this subsection shall be conducted in accordance with 29 Del.C. Chapters 100 and 101, and §4.13 of these regulations.

4.16 Waiver

- 4.16.1 An application for a waiver from any specific requirement of these regulations shall be made in writing to the Division's Director of Quality Assurance, and 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 shall make a recommendation of action on the application to the Division Director or designee. The Director or designee will review the request and recommendations and make final waiver request decisions.
- 4.16.2 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.
- 4.16.3 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 these regulations.

- 4.16.4 An adverse decision by the Division on a request for a waiver may be appealed in accordance with these regulations.
- 4.16.5 The granting of a waiver does not constitute a modification of any requirement of these regulations.
- 4.16.6 Licensees shall notify the Division within ten (10) working days when a waiver granted by the Division is no longer needed.
- 4.16.7 The Director may revoke a waiver when the alternative practice proposed in the application for waiver is determined to be ineffectual.
- 4.16.8 The Director may revoke the waiver when the agency or program fails to implement the alternative practice as proposed in the application for waiver.

Part II: Agency Governance and Administration

Section 5.0 Governing Body

- 5.1 Each agency shall have a board of directors ("board") that serves as the governing body. An agency that is either a for-profit entity or a not-for-profit entity that is part of a national organization providing services in Delaware may have a local advisory board that functions in lieu of a board of directors under these regulations.
- 5.2 Board membership shall include representatives of the surrounding community, and the population it serves including a minimum of 30% combination of current and/or former consumers of behavioral health services, and family members of same.
- 5.3 Members shall sign conflict of interest statements, and forms indicating their agreement to comply with Federal and State regulations concerning client confidentiality.
- 5.4 The board of directors shall adopt by-laws defining the structures, activities, requirements and responsibilities for the corporate governance, and the oversight of the agency's operation and performance.
- 5.5 The bylaws shall clearly define the authority and duties of the governing body, its officers and committees, and include at a minimum:
 - 5.5.1 Ensuring that the administrator, chief fiscal officer, clinical and program directors, clinical supervisors and counselors employed by the agency meet applicable professional credentialing, education and licensing standards and any other qualification requirements of these regulations and as stipulated in any contracts with the State of Delaware; and
 - 5.5.2 Approving and reviewing, at least annually, all policies and procedures governing the management of the agency and its programs including, but not limited to:
 - 5.5.2.1 Administrative policies and procedures;
 - 5.5.2.2 Fiscal management policies and procedures;
 - 5.5.2.3 Program and services policies and procedures;

- 5.5.2.4 Personnel policies and procedures; and
- 5.5.2.5 Environment of care policies and procedures.
- 5.6 The board shall be legally responsible for: overseeing all corporate matters, fiscal management and administrative and programmatic operations of the agency; compliance with applicable laws and regulations; and approving the agency's:
 - 5.6.1 Corporate by-laws;
 - 5.6.2 Mission and vision statements;
 - 5.6.3 Agency and program strategic plan and goals;
 - 5.6.4 Annual report;
 - 5.6.5 Performance improvement plan;
 - 5.6.6 Corporate compliance plan and annual report; and
 - 5.6.7 Operating and capital budgets
- 5.7 Operating and capital budgets
 - 5.7.1 The board of directors shall ensure availability of resources necessary to provide adequate staffing, buildings and grounds, and equipment to facilitate the delivery of quality behavioral health screening, assessment, and treatment services.
 - 5.7.2 The board shall be responsible for ensuring that the agency functions in full compliance with Federal and State regulations regarding confidentiality of clients, their personal health information, and clinical records.
- 5.8 Meetings and Minutes of Meetings
 - 5.8.1 The board shall meet, at a minimum, two (2) times per year.
 - 5.8.2 Minutes of all board of directors and board committee meetings shall include:
 - 5.8.2.1 Names of members who attended;
 - 5.8.2.2 Names of members absent or excused;
 - 5.8.2.3 Date of meeting;
 - 5.8.2.4 Topics discussed, decisions reached, and resolutions adopted; and
 - 5.8.2.5 Documentation of its annual reviews.
 - 5.8.2.6 The minutes shall be available for review by all agency employees and by the Division.
- 5.9 Administrator
 - 5.9.1. The governing body shall appoint an agency administrator who shall be operationally responsible for:
 - 5.9.1.1 The daily management and operation of the agency;
 - 5.9.1.2 Adherence to rules, regulations, standards, and policies pertaining to the health and safety of

clients;

- 5.9.1.3 Compliance with confidentiality regulations and clients' rights as described in these regulations;
- 5.9.1.4 Planning, organizing, and directing activities as may be delegated by the board; and
- 5.9.1.5 Ensuring that the mission, vision, values, and practices of the agency reflect a recovery orientation.
- 5.9.2 The qualifications, authority, and duties of the agency administrator shall be defined in writing.
- 5.9.3 The administrator shall be accountable directly to the chairperson of the board of directors.

Section 6.0 Corporate Compliance and Ethics

- 6.1 The agency shall have a corporate compliance plan that is approved annually by the board of directors.
 - 6.1.1 The plan shall include a whistleblower policy, adopted by the board, to protect any person who reports potential violation of any law, regulation, code, ethical standard, or agency policy from retaliation, harassment, or similar negative consequence for having made such report.
- 6.2 The administrator shall employ or assign a corporate compliance officer (CCO) who reports directly to the administrator, or to a designee who reports directly to the administrator.
- 6.3 The purpose and activities of the corporate compliance officer shall include:
 - 6.3.1 Communicating the business and professional practice standards of conduct by which all agency employees and volunteers are expected to comply;
 - 6.3.2 Advising all employees, volunteers, and contractors regarding the agency's adherence to compliance with all statutes, regulations, and guidelines applicable to their status as a not for profit corporation, for-profit corporation, or state-operated entity, State laws, and Federal laws (including Medicaid regulations), accrediting bodies, and local codes and ordinances;
 - 6.3.3 Ensuring that the agency maintains compliance with Division regulations and contractual obligations;
 - 6.3.4 Continuously auditing and monitoring the agency's operational activities and business practices;
 - 6.3.5 Investigating any reported or suspected violations of any compliance or ethics provision;
 - 6.3.6 Ensuring consistent enforcement of standards and procedures through prompt response and appropriate corrective action; and
 - 6.3.7 Reinforcing that all employees and volunteers support a culture of honesty and integrity, and that the agency expectation is that they report any suspected violation of legal or ethical conduct by others.
- 6.4 A corporate compliance report shall be provided to the board by the administrator

at least annually.

- 6.5 Matters of compliance having urgency and high importance shall be reported to the Board in a timely manner.
- 6.6 Matters of compliance concern involving the administrator shall be brought directly to the board chairperson by the compliance officer. In such cases, the compliance officer shall be relieved of further involvement by the chair, and afforded full whistleblower protection.
- 6.7 The agency shall have a written Code of Ethical Conduct (Code) that addresses ethical issues in the management and provision of services, and that provides governance in the implementation of clinical practices.
- 6.8 Professional staff shall adhere to both the Code of Ethics of their respective disciplines and the agency's Code of Ethical Conduct (Code). Non-licensed staff should be introduced to and trained in the Human Service Worker "code of ethics" that shall be adopted to govern non-licensed staff. The agency's Code of Ethics, if desired and separate from the nationally recognized professional and un-licensed ethic codes, can set higher standards than these codes.
- 6.9 The Agency's Ethics Code(s) shall apply to all staff, volunteers, board members, and consultants, and shall include but not be limited to the following:
 - 6.9.1 Staff shall use accurate and respectful language in all communications with and about clients;
 - 6.9.2 Staff shall be prohibited from engaging in or promising to engage in any personal, scientific, professional, financial, or other dual relationships that are outside their professional relationships within the agency, with persons either currently or formerly served by the agency; and
 - 6.9.3 Staff shall not take advantage of any professional relationship or exploit other staff or clients for their personal, religious, financial, political or business interests.
- 6.10 DSAMH state employees are prohibited from engaging in any kind of business enterprise with any licensed DSAMH agency, program, or service to meet personal or professional needs regardless of compensation.
- 6.11 The Agency's Ethics Code(s) shall define ethical practices for marketing, client recruitment, and discharge for non-payment of fees.
- 6.12 The Agency's Ethics Code(s) shall include a policy prohibiting gifts, goods, or services to be given to, or received from, clients other than the use of evidence-supported treatment incentives (e.g., contingency management) approved by the Division.
- 6.13 The Agency's Ethics Code(s) shall be posted in a conspicuous place(s) in all buildings where services are provided and shall be communicated to all personnel and to all clients during orientation to the agency and shall be available upon verbal or written request.
- 6.14 Orientation regarding these Ethics Codes shall be provided on hire and periodically to all staff, volunteers, and board members.
- 6.15 A record of this orientation shall be maintained by the agency.
- 6.16 The agency shall have a written policy and procedure to address any violation of the Code(s).
- 6.17 All staff and volunteers affiliated with the agency shall sign a copy of the Agency's Code(s) relevant to them to indicate that they understand their responsibility to abide by its expectations.

- 6.18 This signed document shall be entered in the individual's personnel file.
- 6.19 The agency shall not take retaliatory or punitive action against any employee or client for their reporting of a possible or perceived violation of any rule, regulation, standard or statute by the agency or by an employee of the agency.

Section 7.0 Fiscal Oversight

- 7.1 The agency shall establish policies and procedures that reflect compliance with generally accepted accounting principles (GAAP), and define fiscal management, operations, controls, responsibilities, and accountability.
- 7.2 The agency shall develop, through the administrator, an annual financial plan that includes an operating budget, revenue generation strategies, investment strategies, and a long-term capital development and expenditure budget.
 - 7.2.1 The plan shall be developed with input from managers and key staff of agency programs, services, facilities, and departments.
 - 7.2.2 A strategy to monitor the implementation of the plan shall be included.
 - 7.2.3 The plan shall include a strategy developed by the board to ensure sustainability of the agency and its programs and services.
 - 7.2.4 The board of directors shall approve the annual financial plan.
- 7.3 The board shall ensure the employment or assignment of a chief financial officer who reports to the administrator, and is responsible for managing financial operations of the agency and its facilities, programs, and services.
- 7.4 The agency shall contract with an independent certified public accountant to conduct an annual audit of the agency's financial status and a review of fiscal management practices.
 - 7.4.1 The auditor shall be selected by, and report directly to, the board.
 - 7.4.2 The audit shall serve as the basis for the agency's annual report.
- 7.5 The agency shall secure insurance coverage to protect the agency, its board, and employees including:
 - 7.5.1 Coverage for damage, injury, or loss of life caused by fire, accident, or any other dangers that might occur during the operation of the agency;
 - 7.5.2 Coverage for any personal funds of residents in the residential programs of the agency;
 - 7.5.3 Liability coverage for authorized drivers of all vehicles owned, leased or operated by the agency; and additional automobile coverage required by law;
 - 7.5.4 Directors' and officers' liability; and
 - 7.5.5 Professional liability coverage for all staff.
- 7.6 If the agency is responsible for funds belonging to the clients, it shall have written procedures that address:
 - 7.6.1 The securing of such funds;
 - 7.6.2 Accounting for any disbursement of such funds;
 - 7.6.3 The expenditure or investment of such funds only with the consent of the client or, if appropriate, his or her legal representative;
 - 7.6.4 Ensuring that, if the funds of the client are invested, the interest earned

accrues to the client; and

7.6.5 Access by the client, or his or her legal representative, to the records of his or her funds.

Section 8.0 Professional Services Oversight

8.1 The board shall have a standing committee whose charge is to provide oversight to agency programs and services and their quality (e.g., program committee). The program committee membership shall include at least:

8.1.1 One (1) board member will a background in, and considerable knowledge of, the behavioral health industry;

8.1.2 One (1) board member who is in recovery from addiction and/or mental illness and who has been a client of publicly funded services in the state of incorporation;

8.1.3 One (1) board member that has considerable knowledge of the agency's fiscal environment; and

8.1.4 Thirty percent (30%) peer members.

8.2 The program committee shall be responsible for the following:

8.2.1 Reviewing utilization and quality reports, including perception of care surveys, on agency programs and services on a continuous basis;

8.2.2 Reviewing critical incidents of a serious and/or persistent nature that hold the potential for negative consequences to client care and/or agency operations;

8.2.3 Reviewing and approving new program development plans and grant applications;

8.2.4 Reviewing and approving any proposed research projects;

8.2.5 Initiating and guiding program evaluations; and

8.2.6 Ensuring that professional services are supervised by senior managers with appropriate credentials and experience.

8.3 The program committee shall report to the agency's board the findings, recommendations, and areas of concern.

Section 9.0 Policies and Procedures

9.1 The agency shall maintain policies and procedures to define and guide agency operations and professional services, and ensure accountability and consistency in the operation of the organization, and its clinical programs and services.

9.2 The policies and procedures shall be reviewed and updated, as necessary.

9.3 The board of directors shall approve all agency policies and procedures and any revisions.

9.4 Policies and procedures shall generally address the following areas at a minimum, along with more specific topics identified throughout these regulations:

9.4.1 Administration

9.4.2 Management structure and accountability

- 9.4.3 Corporate compliance and ethics
- 9.4.4 Performance improvement
- 9.4.5 Clients' rights
- 9.4.6 Confidentiality
- 9.4.7 Fiscal operations
- 9.4.5 Human resources
- 9.4.6 Environment of care
- 9.4.7 Professional Services
- 9.4.8 Treatment documentation
- 9.5 The agency shall establish a process for ongoing departmental review of policies and procedures, and for endorsing proposed revisions for presentation to the board for final approval.
- 9.6 Procedures shall provide for the continuous monitoring and auditing of internal adherence to written policies and procedures by management and by the corporate compliance officer.
- 9.7 The policies and procedures shall be available to the Division for review on- or off-site.
- 9.8 The agency shall be accountable to the Division for adhering to current written policies and procedures and for maintaining documentation to support compliance.

Section 10.0 Research

In the event that research, experimentation, or clinical trials involving human subjects is to be conducted, it shall be approved by the board, and the agency shall adhere to the following guidelines and to all applicable State and Federal laws and regulations.

- 10.1. A proposal outlining the research, experimentation, or clinical trial must be submitted to the board of directors. The proposal shall include:
 - 10.1.1. The purpose of the study, and its relation to the mission statement and values;
 - 10.1.2. A description of the benefits expected;
 - 10.1.3. A description of the potential discomforts and/or risks that could be encountered;
 - 10.1.4. A full explanation of the procedures to be followed;
 - 10.1.5. The criteria for inclusion and exclusion;
 - 10.1.6 The process to be used to explain the procedures to the subjects of the study, experiment, or clinical trial;
 - 10.1.7. The authorization form/informed consent to be used; and
 - 10.1.8. The method of addressing privacy, confidentiality and safety.
- 10.2 An authorization form shall include all of the elements listed above and:
 - 10.2.1. The name and credentials of the person who supplied the information;
 - 10.2.2. The signature and date of such person; and
 - 10.2.3. The process for the subject to withdraw at any point, without

compromising his or her access to the agency's services.

- 10.3 If research is proposed in connection with an academic institution, the agency shall be required to provide documentation verifying that the research has been reviewed by the university's human subject review committee.
- 10.4 Upon completion of the research, the agency shall ensure that actions are taken to alleviate, to the extent possible, any confusion, misinformation, stress, physical discomfort or other harmful consequences that may have arisen with respect to any participant's right to privacy, confidentiality, or safety.

Part III: Facility and Program Management

Section 11.0 Management Structure and Accountability

- 11.1 In the daily operation of the agency, the agency administrator and management team shall promote principles that are primarily focused on three areas: 1) recovery from behavioral health conditions; 2) care that is trauma-informed, and 3) services and supports that are evidence-based, as defined by SAMHSA.
- 11.2 The management structure of the agency and its programs and services shall be illustrated in a table of organization showing direct lines of accountability and supervision.
- 11.3 The agency administrator and management team of each program or service is responsible for:
 - 11.3.1 Developing and implementing policies and procedures that guide the provision of service and the recovery and wellness of clients;
 - 11.3.2 Integrating the program or service into the primary functions and goals of the agency and other agency service components;
 - 11.3.3 Overseeing continuous assessment and improvement of the quality of treatment and services, and involving clients in the design and evaluation of services;
 - 11.3.4 Ensuring that the defined rights and responsibilities of clients and of staff are enforced; and
 - 11.3.5 Reviewing and acting on reports and recommendations from committees, programs, services, and from clients.
- 11.4 Responsibility for day-to-day administrative and clinical direction shall be defined in writing and included in specific job descriptions.
- 11.5 A qualified behavioral health professional with appropriate clinical training, education, credentials and experience shall be responsible for the clinical direction of treatment programs and service delivery.
- 11.6 The agency administrator and management team shall ensure that the processes for identifying and managing adverse events are defined and implemented. These processes shall include, but shall not be limited to:
 - 11.6.1 Creation of a process for the reporting of adverse events through established channels within the agency, and to external agents in accordance with law and regulation; and
 - 11.6.2 Documentation of a risk-reduction strategy and action plan that includes measurement of the effectiveness of the process and the system

improvements implemented to reduce risk.

- 11.7 The agency administrator shall allocate sufficient resources for assessment and improvement of the agency's governance, managerial, clinical and support processes.
- 11.8 The agency administrator and management team shall evaluate their agency's effectiveness in improving performance on at least an annual basis and report the findings directly to the board.
- 11.9 No provider clinical supervisor shall be expected to supervise more than 10 direct reports.

Section 12.0 Human Resources

- 12.1 The agency shall establish written personnel policies and procedures that shall include, at a minimum:
 - 12.1.1 Staff rules of conduct consistent with due process including:
 - 12.1.1.1 Examples of conduct that constitute grounds for disciplinary action;
 - 12.1.1.2 Examples of unacceptable performance that constitute grounds for disciplinary action;
 - 12.1.1.3 Policies and procedures on mental health and substance use problems of staff (including employee assistance policies and procedures); and
 - 12.1.1.4 Safety and health of staff, including:
 - 12.1.1.4.1 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.
- 12.2 Each agency shall maintain a personnel file for each staff member and volunteer in a manner that ensures confidentiality.
- 12.3 The personnel file shall include at a minimum:
 - 12.3.1 The name and telephone number of a person the agency can contact in an emergency;
 - 12.3.2 The current job title and job description signed by the staff member;
 - 12.3.3 An application for employment signed by the staff member;
 - 12.3.4 A copy of the staff member's active professional license(s) and/or counselor certification(s);
 - 12.3.5 The results of reference investigations and verification of experience, training, and education, including:
 - 12.3.5.1 Primary source verification of the staff member's educational degree certificate(s), based on job description; and
 - 12.3.5.2 Primary source verification of the staff member's license(s), and/or certification(s), as applicable, based on job description;
 - 12.3.6 A Criminal Background Check (CBC) done on first hire and before any staff person is promoted.

- 12.3.7 A statement signed by the staff member acknowledging that s/he understands the requirements of 42 USC §290dd-2, 42 CFR Part 2, and 45 CFR parts 160 and 164 as well as compliance with the Health Insurance Portability and Accountability Act and provisions under the Affordable Care Act of 2010;
- 12.3.8 Copies of the staff member's signed, annual written performance evaluations;
- 12.3.9 Documentation of any disciplinary action taken against the staff member;
- 12.3.10 Documentation of formal corrective action taken, signed by the staff member and supervisor;
- 12.3.11 A copy of the staff member's training plan, as required in these regulations; and
- 12.3.12 Documentation of in-service training and continuing education as required by these regulations, or required for renewal of a license or certification.
- 12.4 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.
- 12.5 Each agency shall establish a written staff training and development plan that shall include:
 - 12.5.1 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:
 - 12.5.1.1 Personnel policies and procedures;
 - 12.5.1.2 Agency 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 Part 2.12(c)(6), including non-retaliation policies when personnel report abuse and neglect;
 - 12.5.1.3 Agency policies and procedures regarding client's rights and protections;
 - 12.5.1.4 Instruction and training in the agency and facility emergency and fire plans; and
 - 12.5.1.5 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.
- 12.6 The basic principles of recovery oriented services, trauma informed care, and the use of evidence-based practices as well as the need to compile data to send to DSAMH on a monthly basis as part of a statewide, ongoing, DSAMH Performance Improvement Planning process.
- 12.7 The agency shall develop programs to promote staff recruitment, recognition, retention, development, and continuing education.
- 12.8 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.

- 12.9 Programs providing co-occurring services shall include training and education specific to co-occurring disorders in the training plan for each staff member, based on the staff member's skill level, education and experience, job functions, and job performance.
- 12.10 Clinical supervisors and all staff providing direct clinical services to clients shall complete a minimum of twenty (20) hours of training and/or education annually, including at least the following topic areas:
 - 12.10.1 Evidence-based treatment of substance use and/or mental disorders.
 - 12.10.2 Evidence-based integrated co-occurring treatment services.
 - 12.10.3 Principles of best practices in Trauma-Informed Care and service delivery ; and
 - 12.10.4 Professional ethics as per discipline, and agency.
- 12.11 Every program utilizing any modalities of adjunctive and alternative therapy shall ensure that individuals providing such services have received specific training and/or credentials applicable to each modality.
- 12.12 All staff, trainees and volunteers shall receive training within the first 120 days of employment about:
 - 12.12.1 Hepatitis;
 - 12.12.2 HIV/AIDS;
 - 12.12.3 Tuberculosis;
 - 12.12.4 Disaster responses;
 - 12.12.5 Other sexually transmitted diseases;
 - 12.12.6 Cardio-pulmonary resuscitation (CPR);
 - 12.12.7 Basic First Aid;
 - 12.12.8 Trauma-informed service delivery;
 - 12.12.9 Recovery-oriented systems-of-care (ROSC);
 - 12.12.10 Fundamental Evidence-Based Practices including at least 1) Motivational Interviewing (MI); 2) Cognitive Behavioral Therapy (CBT); 3) Illness Management ((IM); 4) Family Psycho-Education (FPE [can be received at NAMI); 5) On Common Ground (OCG); 6) ACT teams 7) Medication Assisted Treatment (MAT) or other SAMHSA EBPs identified on the NREPP website (<http://nrepp.samhsa.gov/>) or otherwise approved by the Division. These EBPs can be negotiated by agency every year based on services provided and agency mission and service population;
 - 12.12.11 Roles, functions, and active employment of peer specialists and recovery coaches; and
 - 12.12.12 Infection control procedures.

Section 13.0 Information Management

- 13.1 The agency shall plan and design information management processes to meet internal and external information needs.
- 13.2 The agency shall have and maintain the ability to report data in an electronic fashion to the Division for such purposes as the Division deems necessary, or as

is required by other funding or oversight entities.

- 13.3 The agency shall establish and maintain records and electronic data in such a manner as to make uniform the system of periodic reporting required by the Division.
- 13.4 Agencies shall provide all requested information, either routine or non-routine, as specified by the Division, in a timely manner. For the most part this data will need to be sent monthly and will include: 1) monthly contacts; 2) services provided; 3) outcomes; 4) recidivism; 5) adverse events; 6) all complaints of abuse and/or neglect; 7) individual staff productivity by week and month; 8) issues identified as requiring assistance; and 9) wait lists for services by number of days and rationale.
- 13.5 All information and data shall be maintained and transmitted in a manner consistent with State and Federal privacy and confidentiality statutes and regulations (e.g., 42 CFR, Part 2; 45 CFR Parts 160 and 164; Health Insurance Portability and Accountability Act; Affordable Care Act of 2010).
- 13.6 Records and information shall be protected against loss, destruction, tampering, and unauthorized access, use, or disclosure.
- 13.7 Any known or suspected data breaches that may contain client or employee identifying information shall be reported to the agency corporate compliance officer for investigation.
- 13.8 In the event the agency ceases operation or is merged with, or acquired by another agency, the agency shall maintain a written policy regarding proper transfer or disposal of records consistent with local, State and Federal laws.
- 13.9 Uniform data definitions and data capture methods shall be used whenever possible.
- 13.10 The format and methods for disseminating data and information shall be standardized, whenever possible.
- 13.11 There shall be a plan for disseminating information to appropriate stakeholders.
- 13.12 The information management process, whether electronic or manual shall:
 - 13.12.1 Design and coordinate the systematic and episodic collection of data to produce meaningful and useful management information;
 - 13.12.2 Interpret, analyze and clarify data to generate reports for management and clinical services to use in quality improvement activities;
 - 13.12.3 Generate and provide access to longitudinal operational and clinical data to measure performance improvement over time;
 - 13.12.4 Compare clinical and non-clinical data year-to-year and among all treatment settings to identify trending information;
 - 13.12.5 Compare internal and external (e.g., state, national) data including data associated with access, service use, and outcomes for populations vulnerable to health disparities (i.e., racial, ethnic, sexual/gender minority groups);--and
 - 13.12.6 Utilize agency information system data for practice improvement and to produce reports to the public and the board.

14.0

Client Records

- 14.1 All agency programs and services shall maintain a clinical record for each client

receiving services using a uniform content format.

- 14.2 Agencies shall establish and maintain a record-keeping system that permits easy identification of and access to individual client records by authorized program staff.
- 14.3 A random sample of treatment records shall be reviewed at least quarterly for completeness, accuracy, and timely completion of all necessary information, and compliance with the documentation standards in these regulations.
- 14.4 Agencies shall have policies and procedures that ensure compliance with all Federal and State regulations regarding storage, archiving and destruction of client records.
- 14.5 Agencies are expected to move toward Electronic Health Records (EHRs). Until then the Division expects that progress notes and orders are legible and do not require interpretation from agency staff during monitoring visits. If this is required, the agency will be put on probation until that issue is corrected.

Section 15.0 Environment of Care

- 15.1 The agency shall plan for and provide a safe, accessible, effective and efficient environment consistent with its mission, services, and applicable federal, state, and local laws, codes, rules, and regulations. The agency shall have processes for:
 - 15.1.1 Conducting risk assessments that proactively evaluate the impact of buildings, grounds, equipment, occupants, and internal physical systems on individuals served, staff, and public safety;
 - 15.1.2 Reporting and investigating all incidents to include property damage or injury that affects individuals served, staff, or visitors;
 - 15.1.3 Ongoing hazard surveillance, including relevant product safety recalls;
 - 15.1.4 Examining safety issues by appropriate agency representatives;
 - 15.1.5 Employing or making happen “secret shopper” functions at least two times per year to see if an objective person finds that agency’s services to be welcoming and accessible; and
 - 15.1.6 Reviewing their system for practices that support, or do not support, the principles of recovery and trauma informed care. These reviews will be provided by external (non-employed) peer staff at least once per year.
- 15.2 The agency shall maintain and implement a plan for the safety of staff and clients.
- 15.3 Safety policies and procedures shall be distributed to all staff.
- 15.4 Reviews shall be conducted annually.
- 15.5 At all sites owned or leased by the agency, first aid equipment, emergency medications, and supplies shall be located in accessible areas and be available to all agency staff during all hours of operation.
- 15.6 The agency shall implement policies and procedures to prevent the possession or use of alcohol or other drugs at all programs and facility sites.
- 15.7 When services or program activities are provided off-site, the agency shall:
 - 15.7.1 Have a policy addressing the safety of clients and personnel;
 - 15.7.2 Provide training related to potential risks and emergency procedures;

and

- 15.7.3 Designate individuals to oversee development, implementation, and monitoring of safety management.
- 15.8 The premises of all the agency's programs and facilities shall be sanitary, in good repair, free from accumulation of combustible debris and waste material, and free from offensive odors.
- 15.9 Smoking shall be prohibited in all agency programs and facility buildings and grounds, and in all agencies and (when transporting clients) in staff vehicles.
- 15.10 The agency shall develop and implement a plan for managing hazardous materials and waste in accordance with applicable local, state and environmental codes and regulations.
- 15.11 The agency shall develop and implement an emergency management plan that addresses the four (4) phases of emergency management activities: mitigation, preparedness, emergency response, and restoration/recovery. The emergency management plan contain policies and procedures for:
 - 15.11.1 Identifying specific procedures in response to a variety of disasters based on a hazard vulnerability analysis performed by the agency including but not limited to, floods, hurricanes, tornados, earthquakes, tsunamis, fires, and manmade disasters. These procedures must include documentation of evacuation plans to facilities that have accepted these plans for that agency.
 - 15.11.2 Notifying the Division and other relevant external authorities of emergencies. For purpose of this licensing section, emergencies are defined as any and all of the following:
 - 15.11.2.1 Disruption of normal service delivery;
 - 15.11.2.2 Any natural or man-made event that adversely impacts, or could potentially adversely impact, the operation of the agency's delivery of services, facility or community served; and
 - 15.11.2.3 Any event that necessitates mutual aid assistance from other behavioral health agencies to maintain operations.
 - 15.11.3 Documenting mitigation actions to be taken by the agency to lessen the severity and impact of any potential disaster;
 - 15.11.4 Documenting performance standards for disaster responses that identify staff skill levels and knowledge of their individual role in the agency's emergency management plan;
 - 15.11.5 Identifying the staff responsible for covering all necessary staff positions and for implementing emergency management activities at each program and facility including a list of staff for pre, during and post emergency situation;
 - 15.11.6 Notifying internal staff of the procedures and modes of communication to be used;
 - 15.11.7 Identifying back-up internal and external means of communication;
 - 15.11.8 Managing space, supplies, and security;
 - 15.11.9 Evacuating all facilities in the event that the environment of care cannot support adequate care and treatment;

- 15.11.10 Conducting at least two (2) drills annually that test emergency management procedures related to potential disasters;
- 15.11.11 Conducting evacuation drills at each treatment facility on each shift at least quarterly;
- 15.11.12 Recording all drills and document corrective action taken;
- 15.11.13 Accessing client information that may be needed in a disaster situation;
- 15.11.14 Providing an orientation and education program for personnel who participate in implementing the emergency management plan;
- 15.11.15 Communicating emergency plans to all personnel and to clients, as appropriate;
- 15.11.16 Defining and integrating the agency's role with community and state emergency response agencies;
- 15.11.17 Providing supportive measures and debriefing assistance for staff who participate in implementing the emergency plan; and
- 15.11.18 Conducting an annual evaluation of the objectives, scope, performance, and effectiveness of the emergency management plan.
- 15.12 The agency shall develop and implement a fire prevention plan that is consistent with all laws and regulations.
- 15.13 The agency shall have equipment appropriate to the needs of the clients and personnel for fire detection and suppression.
- 15.14 If State or local fire officials withdraw or restrict safety or occupancy approval for a building in which the agency provides services, the agency shall notify the Division orally within twenty-four (24) hours and in writing within forty-eight (48) hours of the withdrawal or restriction.
- 15.15 If a building is structurally renovated or altered after the initial fire safety approval is issued, the agency shall submit, from the appropriate fire safety authority, the new occupancy approval or written certification that a new fire safety approval is not required.
- 15.16 At all agency facilities, fire exit drills shall be conducted and documented:
 - 15.16.1 At least quarterly in non-residential facilities.
 - 15.16.2 At least one (1) per-shift per-month in residential facilities.
- 15.17 Fire drill documentation shall be maintained and shall include:
 - 15.17.1 Name of person conducting drill;
 - 15.17.2 Date and time of drill;
 - 15.17.3 Amount of time taken to evacuate the building;
 - 15.17.4 Type of drill (obstructed or unobstructed); and
 - 15.17.5 Record of problems and steps taken to correct them.
- 15.18 The agency shall develop and implement a plan to monitor, test and inspect all utilities and equipment, including medical equipment.
- 15.19 Safety self-inspections conducted by the agency shall:
 - 15.19.1 Occur twice each year;
 - 15.19.2 Occur at all agency facilities; and

- 15.19.3 Be documented, to include:
 - 15.19.3.1 Identification of areas inspected; and
 - 15.19.3.2 Corrective actions taken in response to deficiencies cited.
- 15.20 Weapons shall be prohibited at all licensed agency site(s), except when carried by licensed peace officers (e.g., police).
- 15.21 Contraband including drugs and alcohol, stolen merchandise, and pornographic materials shall be banned from all facilities.
- 15.22 The agency shall establish an environment that meets the needs of individuals served, promotes their rights, and respects their human dignity.
- 15.23 Waiting or reception areas shall be comfortable and adequately accommodate visitors and potential clients.
- 15.24 Restrooms shall be available and accessible for staff and clients.
- 15.25 The agency shall maintain a written infection control plan to reduce the risks of infection among clients and staff.
- 15.26 The agency shall have in place policies and procedures to reduce the introduction, and control the spread and effects, of endemic and epidemic infections among clients and staff. These policies and procedures shall address:
 - 15.26.1 Prevention;
 - 15.26.2 Surveillance;
 - 15.26.3 Identification; and
 - 15.26.4 Control of infection
- 15.27 Infections acquired or brought into the agency shall be reported to the administration, appropriate staff, and public health authorities as required by local , State, and Federal regulations.

Section 16.0 Performance Improvement

- 16.1 Every agency shall have a written performance improvement plan.
- 16.2 The performance improvement plan shall be reviewed and revised annually by the governing body.
- 16.3 The performance improvement plan shall provide for the review of:
 - 16.3.1 Clinical services and programs;
 - 16.3.2 The provision of culturally competent services;
 - 16.3.3 Professional services;
 - 16.3.4 Administrative services;
 - 16.3.5 Infection control; and
 - 16.3.6 Environment of care.
- 16.4 The results of performance improvement review shall document:
 - 16.4.1 The problem(s) identified;
 - 16.4.2 The recommendations made;
 - 16.4.3 The action(s) taken;

- 16.4.4 The individual(s) responsible for implementation of actions; and
- 16.4.5 Any follow-up activities to be conducted.
- 16.5 Every agency shall develop and implement program performance and outcome indicators and assess itself against the outcome measures at least annually.
- 16.6 Every program shall provide a mechanism to collect opinions from service recipients, personnel, referral sources, and other stakeholders regarding the quality of service provided. Information shall be submitted to the appropriate governing body committee for review.
- 16.7 Every program shall conduct a needs assessment at a minimum of every five (5) years. The results of the needs assessment should determine staffing patterns and types of services to be provided with changes and updates recorded as part of the agency's performance improvement plan.
- 16.8 Each agency shall develop an annual written performance improvement plan that identifies the agency's performance goals and priorities for the year. The agency shall:
- 16.8.1 Outline at least one (1) specific improvement goal for Parts II through VI of these regulations and for each major program operated by the agency;
- 16.8.2 Monitor the implementation of the performance improvement plan and make revisions as needed;
- 16.8.3 Prepare an annual written summary that reports on the extent to which the annual performance improvement plan was achieved;
- 16.9 The agency shall use performance measures and data collection to monitor its performance and to identify and prioritize opportunities for improvement.
- 16.9.1 Data shall be collected on what the agency considers to be critical processes and outcomes;
- 16.9.2 Data collection shall be prioritized based upon mission-critical functions, services provided, and populations served; and
- 16.9.3 Data shall be collected to monitor improvements;
- 16.9.4 Data shall be collected as required by contract and/or specific Division priorities.
- 16.10 Critical incidents shall be reviewed and addressed by agency management as part of the performance improvement program.
- 16.11 Serious adverse events shall be reported to the Division as immediately as possible.
- 16.11.1 Serious adverse events shall undergo intensive analysis with root causes identified.
- 16.11.2 Actions designed to prevent the same or a similar serious adverse event from recurring shall be identified and implemented.
- 16.11.3 Adverse events that involve the death or arrest of a current or recently discharged client shall be reported immediately to the Division.

Part IV: Clients' Rights and Protections

Section 17.0 Rights of Clients in all Programs and Services

- 17.1 The agency shall maintain a written statement of the Rights of Clients for individuals receiving services and those requesting services.
- 17.2 In all buildings where services are provided, the agency shall display a copy of the Rights of Clients, as defined in these regulations, in a conspicuous place(s), (to include waiting rooms; in facilities where there is no waiting room they shall be displayed in the public/common area).
- 17.2.1 The posted rights shall contain information on how an individual may obtain a copy of the Rights of Clients.
- 17.3 Each client shall receive a written statement of his or her rights that shall contain, at a minimum, the following rights:
- 17.3.1 To be informed of his or her rights during admission or orientation to the agency, whenever the agency makes a change in the rights of clients and upon the verbal or written request of the individual;
- 17.3.2 Receipt of this information shall be documented in the clinical record and validated by the signature of the client. If the person is unable or unwilling to sign such shall be recorded;
- 17.3.3 To express a concern or complaint about services, staff or the operation of the agency:
- 17.3.3.1 The client shall be informed of the agency's concern and complaint resolution procedure during orientation to the agency, whenever there is a change in the procedure, and upon the verbal or written request of the individual; and
- 17.3.3.2 Receipt of this information shall be documented in the client record and validated by the signature of the client. If the person is unable or unwilling to sign, such shall be recorded;
- 17.3.4 To be encouraged and assisted throughout treatment to exercise his or her rights without fear of discrimination, restraint, interference or recrimination;
- 17.3.5 To be informed of his or her rights and to receive services in a language and form he or she understands;
- 17.3.6 To not have services denied for any discriminatory reason, including race, religion, gender, sexual orientation, gender expression, ethnicity, age, disability or source of financial support;
- 17.3.7 To receive the following information about the agency upon admission or during orientation and upon verbal or written request throughout the course of treatment:
- 17.3.7.1 Accreditation status
- 17.3.7.2 Discharge policies
- 17.3.7.3 Areas of treatment specialization
- 17.3.7.4 Hours of operation

- 17.3.7.5 Emergency contact procedures
- 17.3.7.6 Concern and complaint resolution procedure
- 17.3.7.7 General services provided by the agency
- 17.3.7.8 The rights of clients
- 17.3.8 To receive a copy of the agency's policy regarding the responsibilities of clients:
 - 17.3.8.1 Before being asked to leave a program or service for not fulfilling the responsibilities of such program or service, the person shall receive the following:
 - 17.3.8.1.1 Assistance in resolving issues, including the option of accessing a behavioral health advocate;
 - 17.3.8.1.2 Assistance in accessing alternative services;
 - 17.3.8.1.3 Written notification of the pending discharge and the individuals rights of appeal.
 - 17.3.8.1.4 To be provided information about the cost of services proposed and those rendered to the client and to his or her family.
 - 17.3.8.1.5 To be provided, upon request, information regarding charges billed to, and payments made by, an insurance company on his or her behalf.
- 17.3.9 To receive, upon request, information about the credentials, training, professional experience, treatment orientation and specialization of individual practitioners and their supervisors.
- 17.3.10 To treatment and services that are considerate and respectful of the individual's values and beliefs.
- 17.3.11 To privacy, security, and confidentiality of personal health information.
- 17.3.12 To be provided treatment and services in an environment free of abuse, neglect, mistreatment, financial exploitation, and any other human rights violation.
- 17.3.13 To be protected from all coercion.
- 17.3.14 To be informed about what to expect during the treatment process.
- 17.3.15 To be informed about, and to participate in, decisions regarding treatment and services and to receive, at least, the following information to facilitate informed decision-making:
 - 17.3.15.1 Current diagnoses;
 - 17.3.15.2 Proposed interventions, treatment, services and medications;
 - 17.3.15.3 Potential benefits, risks, and side effects of proposed interventions, treatment, services, and medications;
 - 17.3.15.4 Potential risks if treatment is not provided;
 - 17.3.15.5 Limitations on confidentiality;
 - 17.3.15.6 Ongoing progress/status regarding treatment goals and objectives;

- 17.3.15.7 Significant alternative medications, treatments, services or interventions, when appropriate;
- 17.3.15.8 The right, to the extent permitted by law, to refuse interventions, treatment, services or medications;
- 17.3.15.9 Projected discharge date and plan.
- 17.3.16 To receive individualized treatment and services, including:
 - 17.3.16.1 Provision of services within the most appropriate and least restrictive setting for the individual;
 - 17.3.16.2 An individualized recovery or service plan that promotes recovery;
 - 17.3.16.3 Ongoing review and mutually agreed upon adjustments of the recovery or service plan; and
 - 17.3.16.4 Competent, qualified and experienced staff to supervise and to carry out the individual's recovery or service plan.
- 17.3.17 To be present and actively participate in the design of his or her recovery plan and in all periodic reviews, and to choose persons to assist in the development and monitoring of the plan.
- 17.3.18 To be offered a copy of his/her recovery plan.
- 17.3.19 To request a review of his/her recovery plan at any time during treatment.
- 17.3.20 To seek an independent opinion from a mental or substance use disorder professional, of his or her choice, regarding treatment and services provided by the agency.
- 17.3.21 To request a change of provider, clinician or service. If the request is denied the individual shall receive a written explanation.
- 17.3.22 To be given reasonable notice of, and the reasons for, any proposed change in the staff responsible for the individual's treatment or service.
- 17.3.23 To object to any changes in treatment, services or personnel, and the right to a clear written explanation if such objection cannot be accommodated.
- 17.3.24 To refuse any treatment, procedure or medication, to the extent permitted by law and to be advised of the potential risks and impact on his or her treatment.
- 17.3.25 To be referred to an alternate service, program or treatment setting if he or she would be better served at a different level of care or agency.
- 17.3.26 To be present and participate in planning continuing care activities and referrals to other services he or she may need.
- 17.3.27 To provide authorization, or refuse to provide authorization, for the release of confidential information to family members and/or others.
- 17.3.28 To provide authorization, or refuse to provide authorization, for family members and others to participate in his or her treatment.
- 17.3.29 To access his or her client record in accordance with applicable State and Federal laws.
- 17.3.30 To be given information regarding his or her pertinent legal rights relative to the representative payee process, when applicable.

- 17.4 Each individual, asked to participate in a research project, shall receive full explanations of the following, in a language and manner that promotes the opportunity for informed choice and authorization:
- 17.4.1 The reason the person is being asked to participate in this particular research;
 - 17.4.2 The treatment being proposed;
 - 17.4.3 Elements of the proposed treatment that are considered experimental research or a clinical trial;
 - 17.4.4 The benefits to be expected;
 - 17.4.5 The potential discomforts and risks;
 - 17.4.6 Alternative services that might benefit him or her;
 - 17.4.7 The procedures to be followed, especially those that are experimental in nature;
 - 17.4.8 Methods of addressing privacy, confidentiality and safety; and
 - 17.4.9 The right to refuse to participate in any research project without compromising his or her access to the agency's services. Refusal to participate may occur at any time during the conduct of the research project.

Section 18.0 Rights of Clients in Residential/Inpatient Programs

In addition to rights of all clients as defined in these regulations, agencies that provide twenty-four (24) hour care shall develop and implement policies and procedures that address the rights of clients receiving services in any residential or inpatient program or service licensed under these regulations.

- 18.1 No resident admitted to any inpatient or residential program shall be deprived of any constitutional, civil or legal right solely by reason of admission. In addition, each resident is entitled to the following rights:
- 18.1.1 To privacy and dignity.
 - 18.1.2 To communicate by sealed mail or otherwise with persons of the resident's choosing.
 - 18.1.3 To be visited privately at all reasonable times, as arranged in advance through residential staff, by his or her personal physician, attorney or clergy.
 - 18.1.4 To vote and participate in political activity with, as needed, reasonable assistance in registering and voting.
 - 18.1.5 To be employed at a gainful occupation insofar as the resident's condition permits, and in accordance with any written program rules, as approved by the Division.
 - 18.1.5.1 No resident shall be required to perform labor that involves the essential operation and maintenance of the facility, or the regular care and supervision of other residents.
 - 18.1.5.2 Residents may be required to perform labor involving normal housekeeping and home maintenance functions as documented in their individualized recovery plans or as delineated in the community residents' rules and regulations.

- 18.1.5.3 Residents may participate in facility maintenance, repair, landscaping, gardening, painting, and food services as appropriate.
- 18.1.6 To attend or not attend religious services.
- 18.1.7 Residents have the right to access an independent behavioral health advocate of their choosing.
- 18.2 Except to the extent that the residential program director determines that a limitation or a denial of any of the following rights would be in the resident's best interests and, further, unless the clinical director documents the good cause reasons for the denial or limitations in the resident's individualized recovery plan, the resident shall be entitled to the following:
 - 18.2.1 To keep and use one's own personal possessions;
 - 18.2.2 To have reasonable access to a telephone to make and receive private calls;
 - 18.2.3 To keep and be allowed to spend a reasonable sum of one's own money for consumer purchases;
 - 18.2.4 To have opportunities for physical exercise and outdoor recreation;
 - 18.2.5 To have reasonable, prompt access to current newspapers, magazines and radio and television programming;
 - 18.2.6 To receive visitors of one's own choosing at reasonable times. Treatment programs may limit or supervise visitors if, in the judgment of a licensed professional, the visits could result in demonstrable harm to the resident and significantly impact their treatment; or when the visitors are suspected of bringing contraband or in any other way are threatening harm to the resident or others. The reasons for the restriction shall be documented in the resident's treatment record, and an advocate shall be notified prior to implementation. Posted reasonable visiting hours must be maintained in each community residence.
- 18.3 The following shall apply when any of the rights listed in these regulations are restricted.
 - 18.3.1 Reasons for the restriction must be explained to the resident.
 - 18.3.2 The resident's recovery plan shall address ways for the resident to gain or regain the restricted right(s) if appropriate.
 - 18.3.3 Restrictions shall be as limited as possible and should not occur if there is an alternative, less restrictive way for the individual to participate in the program and attain his or her treatment/recovery goals.
 - 18.3.4 All restrictions shall be reviewed by the treatment team and the program administrators within thirty (30) days of implementation and at least quarterly thereafter.
 - 18.3.5 At a resident's request, information about such restrictions shall be forwarded to family members.
- 18.4 Every effort shall be made by the agency to give a prospective resident an opportunity to visit the agency's residential program prior to admission. The prospective resident shall participate in making the decision regarding his or her admission.
- 18.5 Individuals served in a twenty-four (24) hour setting who want spiritual support or services shall have reasonable access to them. Access to spiritual support or

- services shall not infringe on the rights of other residents.
- 18.6 Residential facilities shall develop and implement written policies and procedures that describe the use and the monitoring of behavioral management interventions.
- 18.7 Behavioral management policies and procedures shall be consistent with applicable Federal and State regulations and include the following:
- 18.7.1 Implementation of behavioral management procedures requires the consent of the client;
- 18.7.2 Clients and, as appropriate their families, shall participate in selecting behavior management interventions;
- 18.7.3 Behavioral management may be implemented and enforced only as interventions that are:
- 18.7.3.1 Agreed to by the client; and
- 18.7.3.2 Included in the client's recovery plan;
- 18.8 The least restrictive alternative shall be used in selecting a behavior management intervention;
- 18.9 Behavioral management goals and objectives must be integrated with the client's other treatment goals and objectives;
- 18.10 When the agency serves as representative payee for the client, the person's benefits may not be used as reinforcers or restrictions in a behavioral management agreement.
- 18.11 A behavioral management agreement that is part of the client's recovery plan shall document:
- 18.11.1 The behaviors that are the target of the plan;
- 18.11.2 The methods to teach appropriate expression of the targeted behavior or alternative adaptive behavior;
- 18.11.3 The procedures to be used;
- 18.11.4 How often, under what circumstances, and by whom the plan will be implemented;
- 18.11.5 The intended result of the behavioral management interventions.
- 18.12 Other clients shall not be requested or assigned to carry out any element of the person's behavioral management plan.
- 18.13 Prohibited interventions include but are not limited to the following:
- 18.13.1 Corporal punishment;
- 18.13.2 Fear-eliciting procedures;
- 18.13.3 Denial of any basic need such as shelter, essential clothing, and an adequate, nutritional diet;
- 18.13.4 Denial of the client's legal rights; and
- 18.13.5 Aversive techniques.
- 18.14 All behavioral management plans shall be developed, implemented, and monitored by employees or contractors trained in behavioral management.
- 18.15 The client has the right to withdraw, at any time, his or her agreement to an element, or to all elements, in a behavioral management agreement or plan and

to be advised of the potential resultant risks and impact on his or her treatment process.

- 18.16 The agency shall identify, educate, and train those staff who will be responsible for the development and implementation of behavioral treatment plans.
- 18.17 Policies and procedures shall specify the mechanism for monitoring the use of behavioral management.
- 18.18 Policies and procedures related to behavioral management shall be available to clients and, as appropriate, to their families, guardians, and advocates.
- 18.19 The agency shall have written policies and procedures that clearly define the use of seclusion and restraint that are approved by the Division.
 - 18.19.1 The agency shall ensure that all direct care staff have received training in client de-escalation and passive physical restraint techniques, and early intervention to minimize the use of physical restraint and seclusion.
- 18.20 The leaders of the agency shall establish safe and therapeutic environments that minimize the need for seclusion or restraint.

Section 19.0 Confidentiality

- 19.1 All clients have the right to have their records kept confidential pursuant to the applicable Federal and State laws and regulations.
 - 19.1.1 Each agency shall at all times protect the privacy of clients and shall comply with all the requirements of the applicable State and Federal confidentiality statutes and regulations.
 - 19.1.2 Each agency shall develop policies and procedures in accordance with all State and Federal laws and regulations with respect to the privacy and confidentiality of the records and identity of clients.
- 19.2 Each client shall have the right to have access to his or her treatment record upon request:
 - 19.2.1 The person's access to the treatment record shall include access to records that were received from third parties and any information or documentation relied upon by the agency to develop a diagnosis and a recovery plan.
 - 19.2.2 When a client requests access to his or her treatment record, the agency shall provide the person with its written policy and procedure outlining the process by which such treatment record can be accessed. This policy and procedure shall include the following:
 - 19.2.2.1 Clients, upon review of their records, shall be informed of their right to disagree with information contained therein and to have a statement of disagreement included in their records; and
 - 19.2.2.2 A process and/or a form, developed by the agency to record such statement of disagreement, shall be available to clients; and assistance to prepare such form shall be provided upon request.
- 19.3 If or when a client authorizes the release of his or her treatment record, the agency shall inform him or her that he or she may revoke such authorization at any time.

- 19.4 Each agency shall provide training for all staff on its policies and procedures with respect to the privacy and confidentiality of treatment records and personal health information.
- 19.5 An agency's violation of any State or Federal confidentiality or privacy statute or regulation shall result in a licensing action by the Division.

Section 20.0 Concern and Complaint Resolution

- 20.1 Each agency shall have a concern and complaint resolution policy with an accompanying procedure. The policy and procedure shall conform, at a minimum, to the following standards:
- 20.1.1 This policy and procedure shall apply to persons receiving services and to former recipients of services.
- 20.1.2 At each step in the process, every attempt shall be made to address the concern or the complaint and to resolve the issue in a quick and equitable manner that is without discrimination or recrimination.
- 20.1.3 The policy shall include a provision for informing the individual of his or her right to:
- 20.1.3.1 Immediately contact an advocate of his or her choice
- 20.1.3.2 Contact the Division, if the person perceives an imminent danger or fears retaliation.
- 20.1.4 A process shall be developed and implemented to record and track complaints.
- 20.1.5 Complaint documents shall be filed, maintained, and analyzed.
- 20.1.6 A process shall be developed for forwarding complaint materials to the Division when a complaint remains unresolved and an appeal is initiated.
- 20.1.7 All agency staff shall be trained during orientation and as needed, on the concern and complaint resolution policy and procedure with emphasis on the skills necessary to address concerns so that an early and equitable resolution is achieved.
- 20.1.8 Documentation of this training shall be maintained in each employee's personnel file.
- 20.1.9 Each agency shall implement a process to address concerns and complaints that includes, at a minimum, the following practices:
- 20.1.10 The individual may express a concern or a complaint to any agency staff member or may enlist the assistance of an advocate to do so.
- 20.1.10.1 The individual shall be offered a copy of the agency's concern and complaint resolution procedure that details the steps in the process.
- 20.1.11 The staff member providing assistance to the individual shall make every attempt to resolve an expressed concern.
- 20.1.12 When a concern is not resolved, such concern shall be considered a formal complaint and the individual shall be offered assistance in writing and submitting the complaint to the corporate compliance officer (CCO) and in accessing an advocate, if requested.
- 20.1.13 All complaints shall be forwarded to the agency's designated corporate

compliance officer.

20.1.13.1 The complaint shall be logged by the CCO, according to the agency's procedures.

20.1.13.2 Within four (4) business days of making a formal complaint, the individual shall receive written and verbal confirmation of the CCO's receipt of the complaint.

20.1.14 Within five (5) business days or less of the receipt of the complaint, the corporate compliance officer shall make an attempt at early resolution.

20.2.14.1 If the issue is resolved, a report noting the resolution shall be forwarded to the program staff person designated by the agency.

20.1.15 If the issue is not resolved, the CCO shall investigate the complaint by gathering the facts and by speaking with the people involved and/or those with collateral information.

20.1.15.1 The investigation shall be completed within fifteen (15) business days or less from the date of the CCO's receipt of the complaint.

20.1.15.1.1 If the issue is resolved, a report noting the resolution shall be forwarded to the DSAMH designated department or staff person.

20.1.16 If the complaint is not resolved, the individual shall be informed of his or her right to appeal to the Division. If the individual exercises this right, assistance shall be offered. The individual shall be reminded of his or her option to choose an advocate and assistance with contacting an advocate shall be offered.

PART V: General Standards of Professional Care – Applicable to All Programs and Services

Section 21.0 Client Intake Screening

21.1 Agencies shall have policies and procedures defining intake screening at each program that conducts intake screening for:

21.1.1 Basic eligibility for the agency's programs and services; and

21.1.2 The need for immediate referral to an urgent or emergency treatment service.

21.2 Any initial client intake screening, conducted prior to an on-site intake assessment at an agency program or service, shall include one or more of the following:

21.2.1 Telephone interview with the applicant by an intake specialist or clinician;

21.2.2 Review of materials received from the applicant or a referent containing clinical information indicating the possible need for services;

21.2.3 Discharge and/or referral summary from a licensed behavioral health practitioner, licensed behavioral health treatment agency, or hospital, indicating the need for continuing treatment; or

- 21.2.4 Telephone, electronic, or written confirmation and results of an assessment conducted by a an assessment center or other agency or program.
- 21.3 Applicants who are found to be clearly ineligible following the initial intake screening shall be referred either back to their source of referral, or provided contact information for more appropriate, alternative services.
- 21.4 The intake screening process shall, at a minimum, include:
 - 21.4.1 Identifying and addressing the immediate and urgent needs of the person;
 - 21.4.2 Determining the need for assessment or treatment either by the agency or by referral to another provider or agency;
 - 21.4.3 Eliciting information from significant others when necessary and available;
 - 21.4.4 Scheduling a face-to-face appointment with the person whenever sufficient information is not available through the telephone screening;
 - 21.4.5 Documenting all requests for services and the dispositions.
- 21.7 The agency shall have written policies and procedures describing the intake screening process that:
 - 21.7.1 Define the roles and responsibilities of intake and other professional staff;
 - 21.7.2 Require gathering and documenting, at a minimum, the following information to determine and to prioritize the type and level of service needed and the appropriate service provider:
 - 21.7.2.1 Demographic information
 - 21.7.2.2 The reason the person or the referring agent is contacting the agency
 - 21.7.2.3 Sufficient information about the person's physical, psychological, and social functioning;
 - 21.7.2.4 The person's immediate need for basic necessities;
 - 21.7.2.5 The person's use of alcohol and other drugs;
 - 21.7.2.6 Pregnancy status;
 - 21.7.2.7 Current medications prescribed to the individual;
 - 21.7.2.8 Risk factors, including suicidal or homicidal ideation or behaviors, to determine the need for emergency or urgent care.
- 21.8 Clearly written criteria for scheduling appointments and for admission shall be established, and include:
 - 21.8.1 Criteria for prioritizing the scheduling of appointments;
 - 21.8.2 Criteria for admitting persons for services:
 - 21.8.2.1 In determining an individual's initial and ongoing eligibility for any service, an agency may not discriminate against an individual based on the following factors:
 - 21.8.2.1.1 The individual's past mental or substance use disorder diagnosis or treatment;

- 21.8.2.1.2 Medications prescribed to the individual in the past or present;
- 21.8.2.1.3 The presumption of the individual's inability to benefit from treatment;
- 21.8.2.1.4 Factors not specified in the program's exclusion criteria that are approved by the Division; and
- 21.8.2.1.5 The individual's level of success in prior treatment episodes.
- 21.8.3 Criteria for denying services;
- 21.8.4 Criteria for referring to other providers.
- 21.9 When a person is found to be eligible for the agency's services, and not in need of immediate or crisis-related services, an intake assessment appointment shall be scheduled within five (5) business days, or later if requested by the applicant.
- 21.9.1 If the agency lacks the resources to begin treatment not to exceed two (2) weeks of the screening date, the agency shall refer the individual to another appropriate provider.
- 21.10 When the screening results in a person not being deemed eligible or appropriate for services by the agency or any of its programs and services, the following procedures, at a minimum, shall be followed:
 - 21.10.1 The person is informed that he or she may speak with the screening supervisor if he or she states his or her situation has not been adequately understood.
 - 21.10.2 The person is informed of the reasons for not being offered services by the agency.
 - 21.10.3 Recommendations are provided for alternative services and referral sources, as appropriate.
 - 21.10.4 The person is informed that appeals or complaints may be directed to the program director or, if they were referred through the Division, to the Division's Eligibility and Enrollment Unit (EEU).
 - 21.10.5 The agency maintains documentation of these actions.
- 21.11 Agency programs and services shall maintain current information readily available to staff about alternative licensed programs and service resources that have been approved by the Division.

Section 22.0 Diagnostic Assessment and Biopsychosocial

- 22.1 A comprehensive, multi-disciplinary, diagnostic assessment and level of care assessment shall be completed for each person who is evaluated for admission to an agency's program or service prior to placement.
 - 22.1.1 The program or service may close the potential admission process if the applicant does not make a scheduled appointment without being excused by the program, and does not subsequently contact the program after 90 days have passed.
 - 22.1.2 Through the assessment process, the following shall be determined and documented:
 - 22.1.2.1 The diagnosis;

- 22.1.2.2 The needs, and expectations identified by the client;
- 22.1.2.3 The type and level of care/treatment to be provided;
- 22.1.2.4 The need for specialized medical or psychological evaluations, and any other additional assessment or consultation;
- 22.1.2.5 The need for the participation of family member(s) or other support persons; and
- 22.1.2.6 The name of the primary clinician and other program staff who will provide treatment, if known.
- 22.2 Assessment documentation shall also include basic demographic data, client history, and an integrated behavioral health disorders clinical assessment summary.
- 22.3 A bio-psychosocial assessment shall be completed within the timeframes established for each level of care.
- 22.4 Review and update of the assessment is an ongoing process as clinically necessary (and as specified in each level of care). Updates shall also be documented in response to the following situations:
 - 22.4.1 Significant changes in the individual's clinical condition, overall condition, or life situation;
 - 22.4.2 Frequent use of crisis intervention services;
 - 22.4.3 Changes in level of care;
 - 22.4.4 Transfer between treatment programs;
 - 22.4.5 When requested by client; and
 - 22.4.6 When objectives are met or expected to be met.
- 22.5 A preliminary recovery plan shall be developed within the timeframes established for each level of care based on the assessment and diagnostic formulation, and that includes input from the client and contains, at a minimum, the following:
 - 22.5.1 Initial goals and objectives to be addressed at each stage of treatment;
 - 22.5.2 Identification of strengths relevant to addressing each treatment goal;
 - 22.5.3 Identification of specific interventions to be utilized and their frequency; and
 - 22.5.4 Identification of the clinicians and staff persons responsible for providing services, and target date to be completed for each objective and intervention.
- 22.6 Unless other requirements are designated for a specific program or service, a more comprehensive recovery plan shall be required within the timeframe required in these regulations for the modality for which the program is licensed.

Section 23.0 Treatment Approach

- 23.1 Each program licensed under these regulations shall ensure that provided services are:
 - 23.1.1 Person-centered;

- 23.1.2 Trauma-informed;
- 23.1.3 Age/developmentally appropriate (e.g., young adults, elderly);
- 23.1.4 Recovery-oriented;
- 23.1.5 Family-focused (when appropriate); and
- 23.1.6 Co-occurring capable (i.e., DDC).
- 23.2 To the extent possible, programs shall maximize exposure of clients to recovery peers, both within the facility (e.g., staff, interns/volunteers, alumni) and in the community (e.g., peer recovery community centers, recovery support groups, etc.)
- 23.3 Based upon multi-disciplinary treatment and recovery planning involving client input, specific evidence-based practices (EBPs) shall be used when deemed effective and appropriate. Examples of EBPs include, but are not limited to:
 - 23.3.1 Brief Self-Directed Gambling Treatment (BSGT)
 - 23.3.2 Cognitive Behavioral Therapy (CBT)
 - 23.3.3 Cognitive Enhancement Therapy (CET)
 - 23.3.4 Dialectical Behavioral Therapy (DBT)
 - 23.3.5 Eye Movement Desensitization and Reprocessing (EMDR)
 - 23.3.6 Medication Assisted Treatment (MAT)
 - 23.3.7 Modified Therapeutic Community for Persons with Co-Occurring Disorders (evidence for “some benefit” for offenders to prevent recidivism)
 - 23.3.8 Motivational Enhancement Therapy (MET)
 - 23.3.9 Motivational Interviewing (MI)
 - 23.3.10 Seeking Safety
 - 23.3.11 Trauma Recovery and Empowerment Model (TREM)
 - 23.3.12 Twelve-Step Facilitation Therapy (TSFT)
 - 23.3.13 Wellness Recovery Action Plan (WRAP)
 - 23.3.14 Psycho-Educational Multi-Family Groups (PMFG)
 - 23.3.15 Trauma-Informed Care
 - 23.3.16 Six Core Strategies To Prevent Conflict and Violence: Reducing the Use of Seclusion and Restraint (6CS)

Other examples of EBPs can be found at SAMHSA’s National Registry of Evidence-based Programs and Practices (NREPP) at: <http://nrepp.samhsa.gov/>.

Section 24.0 Recovery Planning and Documentation

- 24.1 Based on the diagnostic assessment and biopsychosocial assessment, a multi-disciplinary planning process that includes the client shall include an outcome-oriented, individualized recovery plan for each client.
- 24.2 The recovery plan will be developed in a person-centered manner with the active

- participation of the client, family, and providers and be based on the client's condition and the standards of practice for the provision of treatment services.
- 24.3 The recovery plan will specify the frequency, amount, and duration of services and must be signed by the counselor, licensed practitioner, or physician responsible for developing the plan with the client (or authorized representative) also signing to note concurrence with the recovery plan.
- 24.4 The recovery plan will address barriers and issues that have contributed to the need for treatment.
- 24.5 Additionally, the recovery plan will:
- 24.5.1 Identify any medical or remedial services intended to reduce the identified condition as well as the anticipated outcomes for the individual.
- 24.5.2 Identify the unique strengths, needs, preferences, expectations, and characteristics of the client into an individualized and comprehensive, recovery-oriented recovery plan.
- 24.5.3 Include the promotion of the client's efforts toward achieving and sustaining recovery, and maximizing general health and wellness both internal and external to traditional mental health supports and treatment and shall directly correlate to the individualized crisis plan.
- 24.6 The responsibility for the overall development and implementation of the recovery plan shall be assigned to a member of the professional staff who has the clinical skills and experience to provide the indicated services. This staff member shall be clearly identified in the plan.
- 24.7 The agency shall develop and implement policies and procedures that promote the participation of clients and their identified support persons in recovery planning sessions. Such policies and procedures shall include, but shall not be limited to the following:
- 24.7.1 The recovery plan shall include the signature of the client or a statement that the client is unwilling or unable to sign.
- 24.7.2 If the client does not participate in the recovery planning process and/or is unwilling or unable to sign the recovery plan, the primary provider shall initiate actions to minimize obstacles and encourage participation. All actions taken shall be documented in the client's record.
- 24.8 The recovery plan shall contain the following elements:
- 24.8.1 A comprehensive DSM-5 diagnosis demonstrating a clear connection between the diagnoses, the data and integrated summary documented in the assessment, and the goals, objectives and interventions to be addressed in the recovery plan.
- 24.8.2 Each recovery goal shall include identification of the client's strengths that shall contribute to his or her achieving the objectives associated with the goals.
- 24.8.3 Long-term goals identified by the client that are recovery-oriented.
- 24.8.4 Short-term goals and objectives formulated by the client and the treatment team as stepping-stones toward the long-term goal(s). Short-term goals and objectives shall be:
- 24.8.4.1 Outcome-oriented;
- 24.8.4.2 Measurable;

- 24.8.4.3 Achievable;
- 24.8.4.4 Congruent with the client's values and beliefs;
- 24.3.4.5 Written in terms the client understands;
- 24.3.4.6 Linked logically and directly with the assessment and the long-term treatment issues;
- 24.3.4.7 Linked to symptom reduction, wellness and to living, learning, and work activities, as appropriate; and
- 24.8.5 Interventions developed to attain each short-term goal and objective shall clearly and specifically indicate:
 - 24.8.5.1 Services, tasks, or support that will help the client attain his or her goals within the timeframes established;
 - 24.8.5.2 When and with what frequency each intervention will occur;
 - 24.8.5.3 The person(s) who will perform or arrange for each intervention; and
 - 24.8.5.4 Timeframes based on the projected length of time to review progress or to achieve each specific goal and intervention.
- 24.9 The recovery plan shall include criteria to be met for treatment to be completed and for the client to be discharged and/or transferred to another level-of care.
- 24.9 The recovery plan for clients with co-occurring substance use and mental disorders shall include treatment goals, objectives and interventions that address both categories of disorders in an integrated approach.
- 24.10 Recovery plans for individuals who have a representative payee shall include treatment goals and interventions designed to help the client manage his or her own finances. Access to funds shall not be contingent upon adherence to treatment goals or participation with treatment.
- 24.11 The recovery plan shall include referrals for needed services that are not provided by the agency and are necessary for the attainment of the client's treatment goals.
 - 24.11.1. The status of the referred and deferred services shall be described in progress notes with outcomes recorded on the recovery plan and in recovery plan reviews.
- 24.12 The recovery plan shall be signed by the primary clinician and by the clinical supervisor of the specific service or program. Each staff person's credentials and the date shall be clearly documented with the signature.
- 24.13 Goals and interventions indicated in the recovery plan shall be reviewed and modified within the timeframes established for each level of care or more often if necessary, and at each of the following events:
 - 24.13.1 Upon significant changes in the client's condition or change in level of care;
 - 24.13.2 When an client refuses services or makes him or herself unavailable for services; and
 - 24.13.3 At the request of the client.
- 24.14 The client and support persons (when authorized by the client) shall be involved

in all reviews and revisions of the recovery plan.

- 24.15 The results of the review must be specifically referenced in the recovery plan and shall be documented in one of the following ways:
 - 24.15.1 On the recovery plan itself;
 - 24.15.2 On a supplement to the recovery plan that is clearly labeled "Recovery Plan Review"; or
 - 24.15.3 In a detailed progress note that is clearly labeled "Recovery Plan Review".
- 24.16 The recovery plan review will involve the client, and as appropriate the family, and providers and it will occur at a frequency specified in each level of care and requires documentation of an evaluation process that includes:
 - 24.16.1 Identifying the reason for the review and the period of time covered;
 - 24.16.2 Gathering information from the client about his or her perception of the treatment process and plans for continued treatment;
 - 24.16.3 Determining whether services have contributed to attainment of recovery goals;
 - 24.16.4 Identifying the factors driving or hindering goal attainment;
 - 24.16.5 Determining the effectiveness and outcome of each treatment intervention;
 - 24.16.6 Considering the recovery plan's responsiveness to the client's strengths, abilities, needs, preferences, and satisfaction;
 - 24.16.7 Reviewing progress notes;
 - 24.16.8 Considering ways the therapeutic alliance may be enhanced; and
 - 24.16.9 Updating, adding, deleting, or revising issue statements, goals, and interventions based on information gained during the course of treatment and the treatment review process.
- 24.17 Recovery plan reviews shall be signed and dated by the primary clinician and clinical supervisor. Recovery plans shall also be signed and dated by the physician, if applicable.
- 24.18 A new recovery plan should be developed if there is no measureable reduction of disability or restoration of functional level. The new plan should identify a different treatment strategy with revised goals and services.

25. Progress Notes

- 25.1 The client's current status and progress relative to the recovery plan and the treatment process shall be documented in progress notes in the treatment record.
 - 25.1.1 Progress notes shall be recorded according to the agency's standard format, unless a standard format is required by the Division.
 - 25.1.2 Progress notes shall be legibly handwritten, typed, or entered electronically.
 - 25.1.3 Each progress note shall be entered in chronological order.
- 25.2 Unless a periodic summary progress note is authorized for a specific program, a progress note shall be recorded for each service contact with a client, family

member, significant other, or a collateral agent approved by the client (e.g., probation officer, referent, community practitioner, facility participating in collaborative healthcare or treatment, etc.).

- 25.3 Progress notes shall include the following information, recorded either manually or electronically, by the providing clinician:
- 25.3.1 Type and duration of service provided;
 - 25.3.2 Date of service;
 - 25.3.3 Objective and subjective observations addressing the client's response to treatment, and any perceived changes in the client's condition;
 - 25.3.4 An assessment, of the client's current functioning and progress toward specific treatment goals and objectives;
 - 25.3.5 Formulation of a plan for specific services or interventions based on the assessment of the client during the service contact.
 - 25.3.6 Signature of the full name of the clinician providing and recording the service including his or her credentials and date;
 - 25.3.7 Requests for and reports of special consultations or evaluations and documentation of review by appropriate staff;
 - 25.3.8 Telephone conversations with the client or with collaterals;
 - 25.3.9 Professional communications regarding the client; and
 - 25.3.10 Cancelled and missed appointments and efforts to remind clients of appointments and any follow up for missed appointments.
- 25.4 Progress notes shall provide documentation of significant life events occurring during the client's course of treatment.

26. Discharge Summary and Continuing Care Plan

- 26.1 A continuing care plan shall be developed in partnership with the client before a planned discharge. The plan shall include:
- 26.1.1 Services to be accessed by the client following discharge;
 - 26.1.2 Activities to sustain the progress made during treatment; and
 - 26.1.3 A crisis plan for the client to follow after discharge.
- 26.2 At the time of the client's discharge from services, a summary shall be formulated that records the most significant information regarding the client's treatment episode. The discharge summary shall include the following:
- 26.2.1 Circumstances of the discharge;
 - 26.2.2 Presenting issues;
 - 26.2.3 Admission and Discharge DSM-5 diagnosis;
 - 26.2.4 All significant findings relevant to the client's treatment and recovery;
 - 26.2.5 Summary of the course and progress of treatment;
 - 26.2.6 Outcomes in relation to the identified issues, goals, and treatment; and
 - 26.2.7 Recommendations and referrals for further services, if indicated.
 - 26.2.8 Signatures of the client, clinician and clinical supervisor.

- 26.3 While discharge planning is begun upon admission, the discharge summary shall be completed within seventy-two (72) hours of any discharge.
- 26.3.1 The client shall be provided a copy of their continuing care plan upon request.
- 26.4 The client shall be discharged from the agency and the treatment record closed if there has been no attempted contact by the client or scheduled appointments for more than 30 days, unless specified otherwise in a particular level of care and unless:
- 26.4.1 The program staff has worked with the client to resolve issues, made appropriate changes in his or her recovery plan, and have documented such efforts.
- 26.4.2 The program staff has assisted the person to access alternative services.
- 26.4.3 The client has been given written notice of the pending discharge and has been informed of his or her right to appeal the decision.
- 26.4.4 Without services, the client is at risk for relapse, hospital level care, incarceration, or homelessness.
- 26.4.5 In the above situation, staff shall make and shall document intensive efforts to contact the client encourage him/her to receive appropriate services.
- 26.4.6 The client is prescribed medication by the agency.
- 26.4.7 The physician or prescribing nurse must authorize the discharge of all clients for whom they prescribe medication.
- 26.4.8 The client has been receiving services and is scheduled to be incarcerated for one (1) year or less.
- 26.4.9 The agency shall continue to advocate for the client to receive appropriate treatment while incarcerated and shall assist with the client's return to the community.
- 26.4.10 A specific program or level of care has other requirements.
- 26.5 When a client does not participate in a planned discharge, prior to the agency processing an administrative discharge and closing the client's record, the agency shall:
- 26.5.1 Provide the client written notice of the pending discharge from treatment and the closure of his or her treatment record.
- 26.5.2 Provide information on how to access emergency services and the conditions, if any, of future care from the discharging agency.
- 26.6 After discharge, follow-up contacts shall be provided as required by specific programs or by State regulations.
- 26.7 The agency is responsible for implementing any additional clinical documentation requirements listed under specific programs or services described in these regulations.

Section 27.0 Pharmaceutical Services -- All Facilities Which Dispense or Administer Medications70

- 27.1 Each facility which utilizes medication as an integral part of treatment shall provide pharmaceutical services to meet the needs of its clients.

- 27.2 The pharmaceutical services shall be conducted in accordance with all applicable Federal and State laws and regulations.
- 27.3 Drug dispensing functions shall be provided through:
- 27.3.1 A community pharmacy or contractual pharmacy services
- 27.3.2 An institutional pharmacy or pharmacist's drug room operated by the facility.
- 27.5 If the facility maintains a pharmacist's drug room, a pharmacist shall:
- 27.5.1 Be responsible for the control of all bulk drugs and maintain records of their receipt and disposition.
- 27.5.2 Compound, dispense or distribute all drugs from the drug room.
- 27.5.3 Monitor the service to ensure its accuracy.
- 27.5.4 The pharmaceutical services shall be under the supervision of a pharmacist.
- 27.6 If the facility operates an institutional pharmacy, the pharmacist shall be responsible for developing, supervising, and coordinating all activities of the service.
- 27.7 When pharmaceutical services are obtained through a community pharmacy, the facility shall have a written agreement with a licensed pharmacist to serve as a consultant on pharmaceutical services.
- 27.7.1 The consultant pharmacist shall visit the facility at least quarterly, to review the pharmaceutical services, make recommendations for improvements and monitor the services to ensure its accuracy.
- 27.7.2 Signed dated reports for each pharmacist's on-site visits with the findings and recommendations shall be kept on file in the facility.
- 27.8 A pharmacist shall be responsible for:
- 27.8.1 Developing procedures for the distribution and controls of drugs and biologicals in the facility.
- 27.8.2 Packaging, labeling and dispensing all drugs to be administered to clients.
- 27.8.3 Monitoring drug therapy for drug interactions and incompatibilities and documentation of the same.
- 27.8.4 Inspecting all areas where drugs are stored (including emergency supplies) to assure that all drugs are properly labeled, stored and controlled.
- 27.9 The facility in consultation with the pharmacist shall develop and implement written policies and procedures for control and accountability, distribution, and assurance of quality of all drugs and biologicals.
- 27.10 Records shall be maintained for all transactions of pharmaceutical services as required by law and as necessary to maintain control of, and accountability for, all drugs and pharmaceutical supplies.
- 27.11 Drugs shall be distributed in the facility in accordance with established procedures.
- 27.12 All drugs shall be dispensed to clients on an individual basis except for pre-determined floor stock medication.

- 27.13 Floor stock shall be limited to emergency drugs, contingency supplies of legend drugs needed to maintain clients during withdrawal management and chemical maintenance and to initiate new therapy, and routinely used non-legend drugs.
- 27.14 Emergency drugs shall be readily available in a designated location(s).
- 27.15 Drugs and biologicals shall be stored under conditions which assure security and environmental control at all storage locations.
- 27.16 Drugs shall be accessible only to persons who are legally authorized to dispense or administer drugs and shall be kept in locked storage at any time such a legally authorized person is not in attendance.
- 27.17 All drugs requiring refrigeration shall be stored separately in a refrigerator used exclusively for medication which is locked or in a locked room.
- 27.18 The inside temperature of a refrigerator, in which drugs are stored, shall be maintained within a 36°F to 46°F range.
- 27.19 Drugs shall be packaged in containers which meet the requirements of the United States Pharmacopeia (USP) for adequate protection from light and moisture.
- 27.20 Drugs to be dispensed to clients shall be packaged in accordance with provisions of the Poison Prevention Packaging Act (15 U.S.C. §§ 1471–1477).
- 27.21 Drugs and biologicals shall be properly labeled.
- 27.22 The label for containers of medication dispensed from an institutional pharmacy or pharmacist's drug room for floor stock use shall include at a minimum the following information:
- 27.22.1 Name and strength of the medication.
- 27.22.2 The expiration date.
- 27.22.3 The lot or control number.
- 27.23 The label for containers of medication dispensed from an institutional pharmacy or pharmacist's drug room for inpatient use shall include at a minimum the following information:
- 27.23.1 Name of the client.
- 27.23.2 Name of the prescribing practitioner.
- 27.23.3 Name and strength of drug dispensed.
- 27.23.4 Lot number and expiration date.
- 27.24 The label of containers of medication dispensed from a community pharmacy for inpatient use shall at a minimum include the following information:
- 27.24.1 Name, address, and telephone number of the dispensing pharmacy.
- 27.24.2 Name of the client.
- 27.24.3 Name of the prescribing practitioner.
- 27.24.4 Specific directions for use.
- 27.24.5 Name, strength, and quantity of drug dispensed.
- 27.24.6 Date of dispensing the medication.
- 27.24.7 Expiration date.
- 27.25 The label for containers of medication dispensed for outpatient use shall at a

minimum include the following information:

27.25.1 Name, address, and telephone number of the dispensing pharmacy or facility.

27.25.2 Name of the client.

27.25.3 Name of the prescribing practitioner.

27.25.4 Specific directions for use.

27.25.5 Name, strength, and quantity of the drug dispensed (unless contraindicated).

27.25.6 Date of dispensing the medication.

27.26 Drugs which are outdated, visibly deteriorated, unlabeled, inadequately labeled, discontinued, or obsolete shall be disposed in accordance with an established procedure which includes the following requirements:

27.26.1 Controlled substances shall be disposed of in accordance with State regulations.

27.26.2 Non-controlled substances and devices shall be destroyed on the premises by a licensed nurse or pharmacist in the presence of another staff person, in a State-approved and environmentally safe manner and so as to render the drugs and devices non-recoverable. The facility shall maintain a record of any such destruction.

27.27 Up to date pharmaceutical reference material shall be maintained in order to provide the professional staff with comprehensive information concerning drugs.

27.28 Facilities shall be provided for the storage, safeguarding, preparation, dispensing, and administration of drugs.

27.29 Any storage or medication administration area shall serve clean functions only and shall be well illuminated and ventilated. When any mobile drug storage cabinet is not being used in the administration of medicines to clients, it shall be stored in a room which meets this requirement.

27.30 When there is an institutional medication room:

27.30.1 Special locked and ventilated storage space shall be provided to meet the legal requirements for storage of controlled substances, flammable fluids and other prescription drugs.

27.30.2 The premises shall be kept clean, lighted and ventilated, and the equipment and facilities necessary for compounding, manufacturing and/or dispensing drugs shall be maintained in good operational condition.

27.31 There shall be written policies and procedures, approved by the medical director, for the safe prescribing and administration of drugs, and the recording of medication administration.

27.31.1 Medication shall be administered only upon written and signed orders of a practitioner acting within the scope of a license.

27.31.1.1 Verbal orders for medications or treatment shall be taken only by personnel authorized by law. The order shall include the date, time, and full signature of the person taking the order and shall be countersigned by the practitioner within 72 hours.

27.31.1.2 Medications not specifically prescribed as to time or

number of doses shall be stopped in accordance with an automatic stop order policy.

27.31.2 Drugs shall be administered directly by a practitioner, physician assistant or by a licensed nurse.

27.31.2.1 Except that the self-administration of medication by clients may be permitted on a specific written order by the physician. Self-administered medications shall be dispensed, stored, monitored and recorded in accordance with an established procedure.

27.31.2.2 When intravenous medications are administered by nurses, they shall be administered only by registered nurses who have specific training and clinical experience in the field of intravenous therapy.

27.31.3 An individual medication record shall be maintained for all clients.

27.31.3.1 All administered, refused or omitted medication shall be recorded on the client's medication record by the individual responsible for administering the medication.

27.31.3.2 Medications given on an "as needed" basis shall be recorded on the client's medication record and a corresponding entry made in the nurses' notes indicating the following additional information:

27.31.3.2.1 The client's subjective symptoms or complaints;

27.31.3.2.2 The time, dosage and route of administration;

27.31.3.2.3 The results of the medication given; and

27.31.3.2.4 The nurse's signature.

27.31.3.3 Medication treatments shall be recorded in the client's record.

27.31.4 Medications administered by the physician shall be recorded in the client's record.

27.31.5 Medication error and apparent adverse drug reactions shall be immediately reported to the attending physician and nurse supervisor and recorded in the client's medical record, and reported to the pharmacist, as appropriate, and described in an incident report.

Section 28.0 Pharmaceutical Services-All Facilities Which Do Not Dispense or Administer Medication

28.1 Each facility which utilizes a self-administration or supervised self-administration of medications system shall develop and implement written policies and procedures governing such system. These policies and procedures shall include:

28.1.1 Identification of the system to be utilized;

28.1.2 Screening of all client medications entering the facility;

28.1.3 Method of obtaining prescription medications;

28.1.4 Storage of medications;

- 28.1.5 Establishment of reasonable controls and/or monitoring methods necessary to assure the safety of all clients and preventing diversion including by staff;
- 28.1.6 Disposal of unused medication and documentation of the method of destruction of controlled and uncontrolled substances using a State-and environmentally-approved method; and
- 28.1.7 At a minimum staff education related to medication shall be conducted on a semi-annual basis.
- 28.2 Facilities which utilize a supervised self-administration of medication program shall provide for the following:
 - 28.2.1 Central, non-portable locked storage areas; and secondary locked storage for controlled substances;
 - 28.2.2 A list of staff members authorized to supervise the self-administration of medications;
 - 28.2.3 A medication self-administration log with staff initials indicating observation of self-administration (two [2] staff initials for controlled substances); and
 - 28.2.4 Supervision of self-administration of medication shall be witnessed and documented in the client record after each dose.

Section 29.0 Tobacco Cessation

- 29.1 Each facility licensed under these regulations shall develop and implement a comprehensive tobacco cessation program which shall include, at a minimum:
 - 29.1.1 Policies and procedures that actively ensure tobacco-free facilities in accordance with these regulations, including buildings and grounds;
 - 29.1.2 Addressing staff tobacco use by providing tobacco cessation supports and incentives, including health insurance coverage, employee assistance programs, and proven effective interventions (e.g., contingency management interventions);
 - 29.1.3 Maintaining a culture among staff that actively supports tobacco cessation and encourages all clients to quit tobacco use; and
 - 29.1.4 Health education and activity programs that include tobacco cessation along with other wellness efforts (e.g., nutrition, exercise).
- 29.2 Each program shall administer the Fagerstrom Test for Nicotine Dependence (FTND) to all applicants at admission; and for all nicotine-dependent clients shall:
- 29.3 Include nicotine dependence in the client's DSM-5 diagnosis;
- 29.4 Identify nicotine dependence in the client's treatment/recovery plan; and
- 29.5 Utilize the Five (5) A's: Ask, Advise, Assess, Assist, Arrange;
- 29.6 Provide cessation supports and/or treatment, depending upon level of care; for example:
 - 29.6.1 In outpatient and low-intensity residential settings where clients have regular access to the community, shall offer nicotine replacement therapy (NRT); tobacco cessation counseling; and/or referral to community services (e.g., Quitline); and
 - 29.6.2 In inpatient and restricted residential programs, provide NRT (e.g., patch

and/or gum) and tobacco cessation counseling to all nicotine-dependent clients immediately upon admission, unless refused by client (and so documented in the client record). Consider utilizing contingency management (CM) interventions.

Section 30.0 Use of Peer Recovery Supports

- 30.1 All agencies shall actively coordinate services with and/or develop peer-based recovery supports and peer-based recovery support services.
- 30.2 All agencies shall provide monthly group supervision with the agency's executive leadership for all agency peer staff.
- 30.3 All agencies shall ensure that clients they serve are engaged with peer recovery supports both while receiving their services and after being discharged, to the extent possible.
- 30.4 These supports shall be in addition to attendance at self-help meetings such as Alcoholics Anonymous and the like.
- 30.5 Such involvement by clients with peers in recovery shall be noted in the clients' record including the recovery plan.
- 30.6 Agencies that provide licensed programs and services shall have qualified service organization agreements with available peer recovery services programs and organizations.

Part VI: Standards Applicable to Specific Categories of Care

Section 31.0 Standards Applicable to All Residential and Inpatient Programs Exceeding 23 Hours

- 31.1 In addition to meeting standards in Part IV concerning Rights of Persons Served in Residential/Inpatient Programs, and Part V concerning General Standards of Professional Care - Applicable to All Programs and Services of these regulations, all residential and inpatient treatment programs and services shall provide:
 - 31.1.1 A physical health nursing assessment by qualified medical personnel on the day of admission, not later than 24 hours after admission, and prior to prescribing.
 - 31.1.2 A physical examination not later than 24 hours after admission unless the client presents a copy of a physical examination completed by qualified medical personnel within 90 days prior to admission, and before medications are prescribed.
 - 31.1.3 A tuberculosis (TB) test administered on the day of admission, and results determined within 72 hours of admission, or documented results of a TB test performed within one (1) year prior to admission.
 - 31.1.4 Testing for Hepatitis and HIV shall be offered and encouraged for all clients, who shall provide written, voluntary consent in order to receive such testing.
 - 31.1.5 A urine sample or other approved test collected just prior to admission or on the day of admission, with a multi-substance drug screen panel analyzed by a certified laboratory.
- 31.2 The expected timeframes for the initial bio-psychosocial assessment, multi-

- disciplinary recovery plan and recovery plan update, and staffing ratios are established for each residential/inpatient level of care.
- 31.3 Programs shall establish 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:
- 31.3.1 A varied and nutritious diet of three (3) meals per-day, seven (7) days per-week;
- 31.3.2 Two (2) snacks each day; and
- 31.7.5 Menus shall be reviewed by a registered dietitian at least annually, and whenever menus are to be substantially changed.
- 31.4 Programs that employ food services staff shall ensure these staff have appropriate experience and qualifications including Safe Serv Certification or documentation of completion of this certification within 12 months of beginning employment; or contract for food services with a commercial food service company to operate the facility's services.
- 31.5 The program 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. Inpatient programs may not offer this.
- 31.6 The program may not mandate payment for meal plans as a treatment requirement.
- 31.7 The program shall provide bedroom space that is safe, clean, and adequately furnished, and that provides:
- 31.7.1 Separation of sleeping quarters serving male and female clients;
- 31.7.2 Separation of bathroom facilities serving male and female clients;
- 31.7.3 Privacy for personal hygiene; and
- 31.7.4 Secure closet and storage space for clients' personal property.
- 31.8 The program must provide security with lock and key for valuables, including an inventory and receipt system.
- 31.9 The program must provide access to a telephone.
- 31.10 The program must provide laundry facilities and supplies for clients.
- 31.11 The program must provide space for solitude.
- 31.12 The program shall ensure that housekeeping services are provided in addition to whatever chores residents may be required to perform.
- 31.13 The program 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.
- 31.14 The program shall document fire drills and other emergency drills completed on a monthly basis and on varied shifts, or according to more stringent accreditation standards if program is accredited.

Section 32.0 Standards Applicable to Opioid Treatment Programs (OTPs) – Federally Certified Programs

An OTP is an organized, ambulatory, addiction treatment service for patients with an opioid substance use disorder and includes patient-centered and recovery-oriented individualized treatment, case management, and health education (including education about human immunodeficiency virus [HIV], tuberculosis, hepatitis C, and sexually transmitted diseases). OTP includes a highly structured environment in which daily attendance at the treatment facility is required (at least until later in a patient's treatment course). Such service should also offer patient-centered addiction counseling and mental health therapy to address the emotional/psychological and behavioral components of the patient's opioid use disorder.

- 32.1 Federal Regulations: all programs licensed under these regulations that provide medication-assisted treatment for opioid use disorders using FDA-approved medications shall be certified as opioid treatment programs (OTPs) by the federal SAMHSA, Center for Substance Abuse Treatment (CSAT), Division of Pharmacologic Therapies (DPT) under 42 CFR Part 8. These shall include opioid medication assisted treatment and ambulatory and/or inpatient opioid withdrawal management programs. Specifically, all OTPs shall:
 - 32.1.1 Comply with applicable regulations of the Drug Enforcement Agency (DEA) concerning storage and handling of medications;
 - 32.1.2 Be accredited by an accrediting body approved by CSAT/DPT (e.g., Joint Commission, CARF, COA);
 - 32.1.3 Be subject to the regulation, oversight and reporting requirements of the State Opioid Treatment Authority (SOTA) as specified by the Division.
 - 32.1.4 Have a written diversion control plan to ensure the safety of clients and accountability for the secure storage of controlled medications.
 - 32.1.5 Have an emergency contingency plan (which must include ongoing contact with the state SOTA) to ensure clients receive medication and services whenever there is a disaster or other circumstances that necessitate the closure of a facility.
- 32.2 Preferred Medications - all such opioid treatment programs shall utilize a variety of medications approved by the DEA and CSAT/DPT and/or recommended by ASAM, including but not limited to: methadone, buprenorphine, and clonidine.
- 32.3 Exceptions – outpatient and residential treatment programs that are not licensed under these regulations as either withdrawal management or opioid treatment programs , but use buprenorphine for opioid treatment shall do so under the DEA license requirements of program physician(s) and are not required to be certified as OTPs.
- 32.4 Medical Necessity - prior to administration of an opioid treatment medication, each client shall be seen by qualified medical personnel and:
 - 32.4.1 Meet current criteria for opioid use disorder of moderate-to-high severity;
 - 32.4.2 Determined to not be enrolled in another OTP, except if being transferred from a detox to an outpatient maintenance program;
 - 32.4.3 Receive a physical examination; and
 - 32.4.4 Demonstrate the presence of opioid withdrawal symptoms.
- 32.5 Client Orientation -- At admission OTPs shall inform clients of:
 - 32.5.1 The facts concerning the use of methadone, buprenorphine, or other opioid treatment medications dispensed by the program, including, but

not limited to:

- 32.5.2 An explanation of the interaction between the opioid treatment medication(s) dispensed by the program and other drugs, medications, medical procedures, alcohol use, and food products, and any potential adverse reactions caused by such interactions;
 - 32.5.3 The importance of notifying the client's primary care physician of their admission to and discharge from the program;
 - 32.5.4 The existence of Delaware's Prescription Monitoring Program (PMP);
 - 32.5.5 The facts concerning the withdrawal from the use methadone, buprenorphine, or other opioid treatment medications dispensed by the program, including, but not limited to:
 - 32.5.5.1 Policies and procedures regarding voluntary, involuntary, and against medical advice (AMA) withdrawal from opioid treatment medications;
 - 32.5.5.2 An explanation of the potential interaction between withdrawal from the opioid treatment medication(s) dispensed by the program and other drugs, medications, and medical procedures;
 - 32.5.5.3 Any potential adverse reactions as a result of withdrawal from opioid treatment medications, including those resulting from interactions with other drugs, prescribed or over-the-counter pharmacological agents, other medical procedures; and
 - 32.5.5.4 The importance of notifying the client's primary care physician of withdrawal from the program.
 - 32.5.6 The program's drug-screening procedure;
 - 32.5.7 The program's opioid treatment medication dispensing procedure, including the days and hours of dispensing;
 - 32.5.8 The program's rules including non-compliance, and discharge procedures, to include administrative opioid treatment medication withdrawal;
 - 32.5.9 The signs and symptoms of overdose and when to seek emergency assistance;
 - 32.5.10 The use of overdose prevention kits (i.e., naloxone);
 - 32.5.11 The emergency procedures maintained by the program as required in these regulations and available 24 hours per-day, including emergency contact information;
 - 32.5.12 Safe storage practices for take-home opioid treatment medications; and
 - 32.5.13 The financial requirements of treatment including consequences for non-payment of required fees.
- 32.6 Upon admission, the program shall obtain from, or issue to, each client a photo identification card.

- 32.7 Pregnant clients -- OTPs shall ensure priority access to pregnant clients seeking treatment.
- 32.7.1 The program 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.
- 32.7.2 An initial dose of methadone shall not exceed 40mg.
- 32.7.3 The program physician shall evaluate dosing of pregnant women monthly during the last trimester of the pregnancy and with increased frequency when clinically indicated.
- 32.7.4 If there is simultaneous use of alcohol and/or other drugs the program shall document:
- 32.7.4.1 Education of the client regarding the potential impact of substance use on the fetus.
- 32.7.4.2 Attempts to encourage the client to cease use of substances other than those prescribed by a physician, and approved by the program physician.
- 32.7.5 Pregnant clients shall be given the opportunity for prenatal care and education, including about Neonatal Abstinence Syndrome (NAS), either by the program or by referral to appropriate health care providers.
- 32.7.6 The program shall document all attempts to assist the client with obtaining prenatal care.
- 32.7.7 OTP's shall maintain 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.
- 32.7.8 No pregnant client shall be involuntarily medically withdrawn from an opioid treatment medication.
- 32.7.9 Pregnant clients 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.
- 32.7.10 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.
- 32.7.11 The program physician shall request the physician, hospital, or program to which the individual is referred, 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.
- 32.8 Essential Personnel -- Each OTP shall have the services of licensed medical personnel including:
- 32.8.1 A designated medical director, who is a program physician with experience and knowledge in medication-assisted opioid use disorder treatment, 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 opioid use disorders;
- 32.8.2 The availability of at least one (1) program physician qualified by training

and DEA approval to prescribe buprenorphine:

- 32.8.3 At all times when the OTP is open, if a program physician is not on-site, a physician shall be available through written contract for consultations and emergency attendance.
- 32.8.4 Each OTP shall have at least one (1) licensed nurse on duty at all times when the program is open.
- 32.9 Staff Orientation -- Prior to services delivery, in addition to training requirements in these regulations, OTPs shall provide orientation to all new staff and volunteers/interns including:
 - 32.9.1 Clinical and pharmacotherapy issues;
 - 32.9.2 Overdose, and other emergency procedures including use of overdose prevention kits (i.e., naloxone);
 - 32.9.3 Provision of services to special populations such as adolescents, pregnant women, and elderly clients; and
 - 32.9.4 Additional orientation regarding opioid treatment medications that is also provided to clients and described in these regulations.
- 32.10 Dosage Procedures and Protocols -- A program physician shall obtain a detailed history of drug use within the last 24 hours prior to initial dose, and:
 - 32.10.1 Determine the client's initial dosage after a physical examination;
 - 32.10.2 The initial dose of methadone shall not exceed 30mg;
 - 32.10.3 Additional methadone doses shall not be administered, unless:
 - 32.10.3.1 After three (3) hours of observation, the program physician documents in the client's record that the initial dose did not suppress opiate abstinence symptoms; and
 - 32.10.3.2 The program physician writes orders for additional medication.
- 32.11 The initial total daily dose of methadone for the first day shall not exceed 30mg unless the program physician documents justification for a higher dosage in the client record that 30mg did not suppress opiate abstinence symptoms.
- 32.12 The initial dose of buprenorphine, and subsequent dosages, shall follow protocols adopted by the Division, unless the program physician justifies otherwise, and documents in the client record.
- 32.13 The program physician shall justify and document in the client record any deviations from dosages, frequencies, and conditions of usage described in the approved product labeling.
- 32.14 Qualified medical personnel shall determine all subsequent dosage levels and shall:
 - 32.14.1 Document each order change on the program physician's medication orders; and
 - 32.14.2 Sign and date each order change.
- 32.15 Unless medically justified by a program physician, or refused by a client, opioid withdrawal management protocols shall follow a 30-day model, as soon as inpatient treatment is no longer required.
- 32.16 Storage and Handling of Medications: in addition to the security requirements of the DEA Regulations Governing Narcotic Treatment Programs (Parts 1301 -

1307 and 42 CFR part 2), the following requirements must be met:

32.16.1 Access to electronic alarm areas where drug stock is maintained shall be limited to a minimum number of authorized medical personnel. Each employee shall have his or her own individual code, which shall be erased upon the employee's termination. A list shall be maintained that identifies all persons with access to the stock/safe and dispensing station and the type of access each has.

32.16.2 All stored controlled substances (powdered, liquid, tablet and reconstituted) shall be clearly labeled with the following information:

32.16.2.1 Name of substance;

32.16.2.2 Strength of substance;

32.16.2.3 Date of reconstitution;

32.16.2.4 Lot number;

32.16.2.5 Reconstituted expiration date or manufacture date, whichever is earlier.

32.16.3 All stored poured doses shall have the following information:

32.16.3.1 Name of substance;

32.16.3.2 Strength of substance;

32.16.3.3 Date of reconstitution;

32.16.3.4 Lot number;

32.16.3.5 Reconstituted expiration date or manufacture date.

32.16.4 Containers shall be kept covered and stored in the appropriate locked safe with access limited through an electronic alarm system that conforms with the DEA requirements of 21 CFR Part 21, Section 1301.71.

32.16.5 Following the initial opioid treatment medication inventory at each OTP, an authorized licensed staff member shall conduct a bi-annual written inventory and document the results. The record is to be maintained for a period of two (2) years. The inventory shall contain:

32.16.5.1 Name and address of the OTP;

32.16.5.2 Date of inventory;

32.16.5.3 Opening or closing of business day;

32.16.5.4 Quantity of opioid treatment medications on hand, amount used, and amount received;

32.16.5.5 Total of all medications accounted for; and

32.16.5.6 Signature of person performing the inventory and a co-signature.

32.16.6 The Division shall be notified of any occurrence of theft, suspected theft, or any loss of any opioid treatment medication. A form, authorized by the Division for reporting adverse events/incidents, shall be completed for each occurrence and shall be sent to the Division, along with a photocopy of DEA form 106.

32.16.7 OTPs shall have quality control procedures to track and trend all spillages of medications with procedures provided by Federal DEA

Regulations (Part 1307.21)

Section 33.0 Standards Applicable to All Co-Occurring Programs and Services

Co-Occurring Capable

- 33.1 All licensed programs shall minimally meet standards for co-occurring capable services.
 - 33.1.1 Programs and services that are primarily organized to serve clients with substance use disorders shall meet criteria as co-occurring capable as measured by the Division's Quality Assurance Unit using a DSAMH-approved instrument.
 - 33.1.2 Programs and services that are primarily organized to serve clients with mental disorders shall meet criteria as co-occurring capable as measured by the Division's Quality Assurance Unit using a DSAMH-approved instrument.

Co-Occurring Enhanced

- 33.2 Agency programs and services licensed under these regulations that serve clients diagnosed with both a substance use disorder and a mental disorder – each of moderate to high severity – shall meet standards for co-occurring enhanced services provision, according to one of the following:
 - 33.2.1 Programs and services that are primarily organized to serve clients with substance use disorders shall meet criteria as co-occurring enhanced as measured by the Division's Quality Assurance Unit using a DSAMH-approved instrument.
 - 33.2.2 Programs and services that are primarily organized to serve clients with mental disorders shall meet criteria as co-occurring enhanced as measured by the Division's Quality Assurance Unit using a DSAMH-approved instrument.

Part VII: Standards Applicable to Specific Programs and Services

Section 34.0 Clinic-Based Assessment and Conflict-Free Case Management Services (PROMISE)

- 34.1 In addition to meeting applicable standards in Parts IV and V of these regulations, all agencies providing clinic-based assessment and case management services shall:
 - 34.1.1 Meet criteria for providing co-occurring enhanced (i.e., COE) services in accordance with standards under Part VI of these regulations.
 - 34.1.2 Operate at least five (5) days per week, including at least two (2) evenings per week.
 - 34.1.3 Operate either as a free-standing facility or, preferably, co-located with other licensed behavioral or primary care health services.
 - 34.1.4 Provide client screening services in accordance with standards outlined in Part V of these regulations, including a determination of the immediate need and, to the extent possible, arranging for:
 - 34.1.4.1 Connecting or reconnecting with existing service provider(s):

- 34.1.4.2 Refer Medically-managed inpatient care for alcohol or other drug withdrawal management services (i.e., ASAM Level 4-WM);
- 34.1.4.3 Emergency or urgent medical or psychiatric care, including the possible need for hospitalization;
- 34.1.4.4 Assistance in accessing prescribed psychotropic medication(s); and
- 34.1.4.5 Emergency or temporary shelter.
- 34.2 If the results of substance use and mental disorders screening is positive, a biopsychosocial and psychiatric assessment will be completed within 4 visits, in accordance with the manual. Additionally an *initial* recovery plan will be developed within 24 hours, and the program shall conduct co-occurring capable (i.e., COC) or co-occurring enhanced (i.e., COE) assessment activities as needed, in accordance with Part V of these regulations, that result in a determination of:
 - 34.2.1 The need for further specialized assessments (e.g., psychiatric, psychological, neuro-psychological, neurological, medical, etc.);
 - 34.2.2 The need for basic and psycho-social needs (e.g., food, clothing, housing, transportation, childcare, etc.);
 - 34.2.3 Healthcare insurance and/or public entitlement enrollment; and
 - 34.2.4 Other case management needs.
- 34.3 Provide clinical case management services, including but not limited to:
 - 34.3.1 Development the full recovery plan after completion of the assessment and within thirty (30) days of admission;
 - 34.3.2 Coordination of care with existing and potential providers;
 - 34.3.3 Coordination of treatment placement with Division EEU staff for all levels of care.
 - 34.3.4 Coordination of outpatient and community support services through the Division's regional care managers, as needed;
 - 34.3.5 Referral to, and facilitation with placement in, needed treatment services;
 - 34.3.6 Motivational interviewing (MI) and engagement;
 - 34.3.7 Brief intervention (BI) counseling services;
 - 34.3.8 Basic outreach when a client is in need of, but avoiding services or treatment placement;
 - 34.3.9 Facilitation of the development of Wellness Recovery Action Plans (WRAP);
 - 34.3.10 Making and following up with referrals to local social services;
 - 34.3.11 Assistance with obtaining basic needs, healthcare insurance and entitlements; and
 - 34.3.12 Location and introduction to peer recovery support services
- 34.4 Provide on-site peer recovery support services including, at a minimum:
 - 34.4.1 Motivational peer counseling;
 - 34.4.2 Peer specialist operated resource center;

- 34.4.3 Peer-run recovery meetings:
- 34.5 Provide dispositional planning that will result in case closure within 30 days, or up to no longer than 90 days, if necessary.
- 34.6 The agency shall provide staffing sufficient to meet the needs of clients to include the services of:
 - 34.6.1 Psychiatrists
 - 34.6.2 Nurses
 - 34.6.3 Licensed clinicians
 - 34.6.4 Alcohol and drug counselors
 - 34.6.5 Peer recovery specialists
 - 34.6.6 PROMISE case managers

Section 35.0 Crisis Intervention (Mobile Crisis Unit)

- 35.1 In addition to meeting standards in Part IV concerning Rights of Clients in all Programs and Services, and Part V regarding General Standards of Care Applicable to all Programs and Services, agencies operating psychiatric crisis intervention shall meet the standards within this section.
- 35.2 Psychiatric/Mobile Crisis Services are available via telephone and/or face-to-face for evaluation 24 hours per-day, seven (7) days per-week.
- 35.3 An accessible phone line for emergency contacts shall be established and the agency shall ensure that a qualified clinician responds within ten (10) minutes of notification from an answering service or from a non-professional staff person.
- 35.4 The facility shall operate mobile crisis services capable of dispatching clinical staff or trained peer interventionists 24 hours per-day, seven (7) days per-week on an on-call basis, as needed to address their client population.
- 35.5 The agency shall establish policies and protocols that, at a minimum, describe the following:
 - 35.5.1 Eligibility, exclusion, admission, and discharge criteria;
 - 35.5.2 Procedures for the provision of emergency medical and emergency behavioral healthcare;
 - 35.5.3 Guidelines for the internal and external transfer, referral, and follow-up care of clients, to include referrals for physical and medication evaluations; and
 - 35.5.4 Procedures for the involvement of significant others during emergency situations.
- 35.6 The following assessment information shall be gathered and documented:
 - 35.6.1 Presenting issue(s);
 - 35.6.2 Mental status;
 - 35.6.3 Level of risk for suicidal, homicidal, or other dangerous behaviors;
 - 35.6.4 Current use of alcohol and other drugs to include consideration of current state of intoxication and need for immediate medical intervention;
 - 35.6.5 Current medications;

- 35.6.6 Drug allergies, idiosyncratic reactions, and/or other adverse effects;
- 35.6.7 Medical conditions;
- 35.6.8 Legal status;
- 35.6.9 Name, and phone number of treating physician(s); and
- 35.6.10 Information from significant others and from current providers when appropriate and available;
- 35.7 The implementation of crisis intervention services shall include, but shall not be limited to, the following:
 - 35.7.1 The program shall have procedures for transferring to a hospital individuals experiencing a medical or psychiatric emergency.
 - 35.7.2 Each program shall employ, either directly or on a consultation basis, the services of one (1) or more QPPs to provide twenty-four (24) hour medical back up as well as: Nurses; Licensed Clinicians; Alcohol and Drug Counselors and Peer Recovery Specialists.
 - 35.7.3 Program crisis intervention staff must have knowledge of the appropriate use of community resources, crisis intervention techniques, and procedures for involuntary hospitalization (inpatient and outpatient).

Section 36.0 23-Hour Psychiatric Crisis Intervention and Stabilization Services

In addition to meeting standards in Part IV concerning Rights of Clients in all Programs and Services and Part V regarding General Standards of Care Applicable to all Programs and Services, agencies operating 23-Hour Psychiatric Crisis Intervention and Stabilization Services shall meet the standards within this section.

- 36.1 Agencies shall ensure that psychiatric crisis services are available 24 hours per day, seven (7) days per-week.
- 36.2 An accessible phone line for emergency contacts shall be established and the agency shall ensure that a qualified clinician responds within ten (10) minutes of notification from an answering service or from a non-professional staff person.
- 36.3 The agency shall establish policies and protocols that, at a minimum, describe the following:
 - 36.3.1. Eligibility, exclusion, admission, and discharge criteria;
 - 36.3.2. Procedures for the provision of emergency medical and emergency behavioral healthcare;
 - 36.3.3. Guidelines for the internal and external transfer, referral, and follow-up care of clients, to include referrals for physical and medication evaluations; and
 - 36.3.4. Procedures for the involvement of significant others during emergency situations.
- 36.4. The following assessment information shall be gathered and documented:
 - 36.4.1. Presenting issue(s);
 - 36.4.2. Mental status;
 - 36.4.3. Level of risk for suicidal, homicidal, or other dangerous behaviors;
 - 36.4.4 Current use of alcohol and other drugs to include consideration of current state of intoxication and need for immediate medical intervention;

- 36.4.5 Current medications;
- 36.4.6 Drug allergies, idiosyncratic reactions, and/or other adverse effects;
- 36.4.7 Medical conditions;
- 36.4.8 Legal status;
- 36.4.9 Name, and phone number of treating physician(s); and
- 36.4.10 Information from significant others and from current providers when appropriate and available.
- 36.5 The implementation of crisis intervention services shall include, but shall not be limited to, the following:
 - 36.5.1 The program shall have procedures for transferring to a hospital individuals experiencing a medical or psychiatric emergency.
 - 36.5.2 Each program shall employ, either directly or on a consultation basis, the services of one (1) or more psychiatrists to provide twenty-four (24) hour medical back up.
- 36.6 Program crisis intervention staff must have knowledge of the appropriate use of community resources, crisis intervention techniques, and procedures for involuntary hospitalization (inpatient and outpatient).
- 36.7 Crisis stabilization services, provided after crisis intervention services, shall require a written recovery plan, formulated with the client that includes, at a minimum, the following:
 - 36.7.1 DSM-5 diagnoses;
 - 36.7.2 Identification of the person's strengths to assist him or her to attain the desired recovery goals;
 - 36.7.3 Stabilization/relapse prevention goals and interventions; and
 - 36.7.4 Plan for treatment after stabilization.
- 36.8 Policies and procedures shall be developed and implemented that address the provision of services for individuals who:
 - 36.8.1 Refuse treatment;
 - 36.8.2 Fail to keep scheduled appointments;
 - 36.8.3 Are unable to or do not follow their recovery plans;
 - 36.8.4 Engage in threats or acts of violence; or
 - 36.8.5 Exhibit behavior disruptive to program functioning.
- 36.9 The agency shall provide staffing sufficient to meet the needs of clients to
include the services of:
 - 36.9.1 Psychiatrists
 - 36.9.2 Nurses
 - 36.9.3 Licensed clinicians
 - 36.9.4 Alcohol and drug counselors
 - 36.9.5 Peer recovery specialists

Section 37.0 Level 2-WM (Withdrawal Management)-23 hour

- 37.1 In addition to meeting standards in Part IV concerning Clients Rights and Protections, Part V concerning General Standards of Professional Care - Applicable to All Programs and Services, and Part VI regarding Standards Applicable to all Residential/Inpatient Programs of these regulations, agencies operating 23-Hour Observation, Evaluation and Referral Services shall meet the standards within this section.
- 37.2 The 23-hour observation program shall be co-located with or accessible to a facility with residential or inpatient withdrawal management services.
- 37.3 The service shall have the ability to accept admissions at any time, and operate 24 hours per-day, seven (7) days per-week.
- 37.4 The agency shall have extensive written agreements for facilitating referrals for continuing care at all levels (e.g., emergency room, inpatient or ambulatory withdrawal management, psychiatric hospitalization, outpatient, etc.). Referral and assistance must be provided as needed for the beneficiary to gain access to other needed Medicaid SUD or mental health services.
- 37.5 Policies and procedures shall stipulate that clients shall not stay longer than 23 hours and 59 minutes, and shall not be readmitted within 24 hours of discharge (as individuals needing immediate readmission are likely to need a higher level of care).
- 37.6 Admission Criteria
- 37.6.1. The facility shall admit clients who present with acute substance use disorder and may also demonstrate low severity mental health symptoms or emotional distress.
- 37.6.2. The client may be at potential risk to self or others but not actively suicidal or homicidal requiring emergency services; but does require observation and assessment by medical and substance use disorder treatment professionals.
- 37.6.3. Clients admitted to the facility shall not be in imminent need of medical or psychiatric hospitalization.
- 37.7. The substance abuse screening shall take place within one (1) hour of the individual's arrival, and include:
- 37.7.1. On-site urine drug screen or other approved test and breathalyzer test;
- 37.7.2. Screen for the need for emergency medical assistance;
- 37.7.3. A mental status examination;
- 37.7.4. A query to the State Prescription Monitoring Program shall be done by a qualified psychiatric provider to validate self-report medication usage; and
- 37.7.5. Physical health screening that shall be conducted by a licensed nurse.
- 37.8. A nursing assessment including a medication evaluation shall be conducted by a registered nurse (RN) at time of admission and within the first three (3) hours and be reviewed by a physician to determine the need for withdrawal management, eligibility and appropriateness (proper patient placement for admission criteria).
- 37.9. A substance abuse/co-occurring screen by a CADC or CCDP or other behavioral health professional working within their scope of practice shall be conducted at

admission and within five (5) hours.

- 37.10. An initial recovery plan with emphasis on crisis intervention, stabilization and motivational enhancement shall be initiated upon admission and completed by a clinician within 12 hours.
- 37.11. Individual and, if possible, family counseling shall be available and offered using a brief intervention/solution-focused approach aimed toward referral and engagement in treatment based upon the assessed level of care needed.
- 37.12 Discharge planning shall be included in the recovery plan, and be the focus of the multidisciplinary team's efforts.
- 37.14 At least one nurse (must be NP, RN) per 12 individuals on site at all times.
- 37.15 A designated prescriber shall be on site as needed; and on-call 24 hours per day, seven (7) days per-week.
- 37.16 At least one (1) peer recovery coach shall be on site per 12 individuals during days and evenings.
- 37.17 At least one behavioral health technician per 12 individuals shall be on site at all times.
- 37.18 Consultation services shall be available for: pharmacology, psychological, emergency medical, laboratory, and other diagnostic services as needed.
- 37.19 Physician orders are required for medical and psychiatric management.

Section 38.0 Outpatient Treatment Services (ASAM Level 1)

In addition to meeting standards in Part IV concerning Rights of Clients in all Programs and Services, and Part V concerning General Standards of Professional Care - Applicable to All Programs and Services of these regulations, agencies operating Outpatient Treatment Services shall meet the standards within this section.

- 38.1 Outpatient Level 1 treatment services are comprehensive, coordinated and defined services that may vary in level of intensity but are fewer than nine (9) contact hours per week provided in an amount, frequency and intensity appropriate to the client's multidimensional severity and level of function. Clients with SUDs will need to meet ASAM Level 1 criteria.
- 38.2 Outpatient treatment services are professionally directed assessment, diagnosis, treatment, and recovery services provided in an organized non-residential treatment setting. Outpatient services include, but are not limited to individual, group, and family counseling, including psycho-education on recovery and wellness and ongoing recovery and disease management services.
- 38.3 Level 1 addiction services are appropriate for any patient after an episode of intensive addiction care (Level 2, 3, or 4).
- 38.4 Outpatient treatment services should include evidence-informed practices, such as cognitive behavioral therapy (CBT), motivational interviewing, multidimensional family therapy, or other Division-approved EBP.
- 38.5 Outpatient Level 1 services are organized activities which may be delivered in any appropriate community setting that meets State licensure standards. Outpatient shall be provided either in a free-standing facility, or co-located with another behavioral health program, a primary healthcare facility, a State-operated clinic, a health home or the like, and other locations pre-authorized by the Division.

- 38.6 Agencies that have more than one (1) outpatient treatment services location shall obtain a license for each location.
- 38.7 A facility/agency license is not required for individual or group practices of licensed counselors/therapists providing these services under the auspices of their individual license(s).
- 38.8 Agencies operating outpatient treatment services shall maintain evening and/or weekend appointment hours adequate to meet the needs of clients.
- 38.9 Level 1 outpatient settings include an array of licensed practitioners, unlicensed counselors, as well as certified peers, and credentialed behavioral health technicians operating within their scope of practice.
- 38.10 Caseload size is based on needs of individuals actively engaged in services to ensure effective, individualized treatment but should not exceed 32 active equivalent individuals (see definition) for each licensed practitioner and unlicensed counselor.
- 38.11 Counseling groups should not exceed 15 individuals (assumed average of 9), while psycho-educational group size is not restricted.
- 38.12 QHP supervisors must be on site or available for phone consultation in a crisis 24/7 and supervise no more than 10 unlicensed staff.
- 38.13 Peers may lead groups and meet with clients 1:1, but would bill peer support unless also meeting certification criteria to be one of the unlicensed counselors.
- 38.14 A diagnostic assessment shall be completed by a qualified substance abuse, mental health or co-occurring disorder practitioner prior to admission to an Outpatient Level 1 program.
- 38.15 Outpatient treatment services must include documentation of a physical examination by qualified medical personnel within 90 days prior to intake.
- 38.15.1 When documentation of a physical examination is not available or obtainable by the second session, staff shall document good faith efforts made to obtain records, or refer the client for a physical examination.
- 38.16 Clients who are actively psychotic, homicidal, suicidal or in need of medication-assisted withdrawal from substances shall not be admitted until they are medically stabilized.
- 38.17 A biopsychosocial assessment for substance use and mental disorders shall be completed by a qualified substance abuse, mental health or co-occurring disorder practitioner within 30 days of admission or by the fourth counseling session.
- 38.18 An *initial* recovery plan shall be initiated by the first session by the primary counselor and must be completed within 30 days of admission or by the fourth counseling session, whichever comes first.
- 38.18.1 The recovery plan shall be signed by the client, the primary counselor and by a licensed clinical supervisor.
- 38.18.2 The recovery plan shall be reviewed and updated at least every 90 days after completion of the plan, or more frequent if clinically indicated, or earlier if there is a significant change required.
- 38.19 Clients who are under separate care with a psychiatrist or prescribing physician or practitioner shall be requested to sign authorization for outpatient services staff to communicate with such provider in order to coordinate care, especially the use of medications.

- 38.20 The outpatient services program may provide, through contractual arrangement, for a psychiatrist or other prescribing physician to prescribe and manage psychotropic medications for clients.
- 38.21 The outpatient service may also arrange for a DEA-approved physician to prescribe buprenorphine/naloxone medication for opiate use disorder using their individual prescribing limit; or similar medications to mitigate opioid withdrawal symptoms.
- 38.22 Agencies providing outpatient treatment services shall develop and implement specific policies and procedures describing:
- 38.22.1 Admission
 - 38.22.2 Continuing care
 - 38.22.3 Discharge criteria
 - 38.22.4 Evidence-based and best practice services available to clients
- 38.23 Outpatient treatment programs (OP) shall provide directly, or through contractual arrangements, the following services:
- 38.23.1 Psychiatric evaluation
 - 38.23.2 Psychological assessment
 - 38.23.3 Individual, family, and group counseling
 - 38.23.4 Multi-family groups
 - 38.23.5 Medication treatment and review
 - 38.23.6 Psycho-educational services for clients and families
 - 38.23.7 Case management services
- 38.24 When needed, the primary counselor or a case manager shall assist the client in obtaining other needed health, rehabilitation, social, and recovery support services.
- 38.25 The agency shall incorporate peer recovery specialists in the conduct of daily operations and services at the outpatient facility, including holding on-site recovery support group meetings.
- 38.26 Discharge planning shall begin at admission, and continuously revised until a discharge date is set.

Section 39.0 Intensive Outpatient Treatment Programs (ASAM Level 2.1)

In addition to meeting standards in Part IV concerning Rights of Clients in all Programs and Services, and Part V concerning General Standards of Professional Care - Applicable to All Programs and Services of these regulations, agencies operating Intensive Outpatient Treatment (IOP) Programs shall meet the standards within this section.

- 39.1 Intensive outpatient treatment services are professionally directed assessment, diagnosis, treatment, and recovery services provided in an organized, non-residential treatment setting. These services include, but are not limited to skilled treatment services that may include: individual and group counseling, management, family therapy, educational groups, occupational and recreational therapy, and other therapies. Services are provided in amounts, frequencies, and intensities appropriate to the objectives of the recovery plan.

- 39.2 Intensive outpatient program services should include evidence-informed practices, such as cognitive behavioral therapy (CBT), motivational interviewing, multidimensional family therapy, or other Division-approved EBP.
- 39.3 These programs offer comprehensive, coordinated, and defined services that may vary in level of intensity but must be a minimum of nine contact hours per week for adults age 18 years and older, with a minimum of contact three days per week. Intensive outpatient programs (IOPs) generally provide 9 - 19 hours of structured programming per week for adults.
- 39.3 Intensive outpatient services may be delivered in any appropriate community setting that meets State licensure. Services shall be provided either in a free-standing facility, or co-located with another behavioral health program, a primary healthcare facility, a State-operated clinic, a health home or the like, or other locations pre-authorized by the Division.
- 39.4 Agencies that have more than one (1) intensive outpatient treatment services location shall obtain a license for each location.
- 39.5 Agencies operating intensive outpatient treatment services shall provide both day and evening tracks to accommodate individuals who are employed.
- 39.6 Level 2.1 outpatient settings include an array of licensed practitioners, unlicensed counselors, as well as certified peers, and credentialed behavioral health technicians operating within their scope of practice.
- 39.7 Caseload size is based on needs of individuals actively engaged in services to ensure effective, individualized treatment and rehabilitation but should not exceed 35 individuals for each licensed practitioner or unlicensed counselor.
- 39.8 Counseling groups should not exceed 15 individuals (assumed average of 9), educational group size is not restricted.
- 39.9 One FTE during clinic hours shall be dedicated to performing referral arrangements for all individuals served by the facility. This FTE may be a licensed practitioner, unlicensed counselor or certified peer.
- 39.10 QHP supervisors must be on site at least 10 hours per week during hours of operation, be available for phone consultation at all times, and supervise no more than 10 unlicensed staff.
- 39.11 A prescriber is part of the interdisciplinary team and must have a face-to-face contact at least every 30 days and more frequently if clinically necessary and be available for phone consultation at all times.
- 39.12 A diagnostic assessment shall be completed by a qualified substance abuse, mental health or co-occurring disorder practitioner prior to admission to an Outpatient Level 1 program.
- 39.13 Documentation of a physical examination by a qualified medical professional within a reasonable time, as determined by the client's medical condition not to exceed within 90 days prior to admission.
- 39.13.1 When documentation of a physical examination is not available or obtainable by the third session, staff shall document good faith efforts made to obtain records, or refer the client for a physical examination.
- 39.14 Clients who are actively psychotic, homicidal, suicidal or in need of medication-assisted withdrawal from substances shall not be admitted until they are medically stabilized.
- 39.15 A biopsychosocial assessment for substance use and mental disorders shall be completed by a qualified substance abuse, mental health or co-occurring

disorder practitioner by the third counseling session.

- 39.16 A recovery plan shall be completed by the primary counselor by the third counseling session.
- 39.17 The recovery plan shall be signed and dated by the client, the primary counselor and by a clinical supervisor.
- 39.18 The recovery plan shall be reviewed and updated every 30 days after completion of the plan, or earlier if there is a significant change required.
- 39.19 Clients who are under separate care with a psychiatrist or prescribing physician or practitioner shall be requested to sign authorization for outpatient services staff to communicate with such provider in order to coordinate care, especially the use of medications.
- 39.20 The outpatient services program may provide, through contractual arrangement, for a psychiatrist or other prescribing physician to prescribe and manage psychotropic medications for clients.
- 39.21 The outpatient service may also arrange for a DEA-approved physician to prescribe buprenorphine/naloxone medication for opiate use disorder using their individual prescribing limit; or similar medications to mitigate opioid withdrawal symptoms.
- 39.22 Groups shall include a combination of substance use disorder-related only; mental disorder-related only; and co-occurring disorder groups in numbers and combinations based upon the needs of the program population at any time, and include a mixture of:
 - 39.13.1 Psycho-educational groups;
 - 39.13.2 Cognitive behavioral therapy (CBT) groups;
 - 39.13.3 Clinical process groups; and
 - 39.13.4 Other specialty groups as determined by clients' needs.
- 39.23 Regular and random urine drug screening or other approved tests as frequently indicated by individual recovery plan.
- 39.24 Program community meetings held on program days, including staff and clients.
- 39.25 On-site recovery meetings at least once weekly.
- 39.26 Intensive outpatient treatment programs (IOP) shall provide directly, or through contractual arrangements, the following services, among others, to meet the collective needs of clients:
 - 39.26.1 Psychiatric Evaluation
 - 39.26.2 Psychological Assessment
 - 39.26.3 Medication treatment and review
 - 39.26.4 Case management services
- 39.28 When needed, the primary counselor or a separate case manager shall assist the client in obtaining other needed health, rehabilitation, social and recovery support services.
- 39.29 The agency shall make every attempt to incorporate peer recovery specialists in the conduct of daily operations and services at the outpatient facility, including holding on-site recovery support group meetings.
- 39.30 Discharge planning shall begin at admission, and continuously revised until a

discharge date is set.

- 39.31 Clients that fail to make four (4) consecutive scheduled sessions without notification or sufficient excuse shall be given 10 business days' notice of pending discharge from the outpatient service using a predetermined client communication method established at admission.

Section 40.0 Ambulatory Withdrawal Management with Extended On-Site Monitoring (Level 2-WM)

In addition to meeting standards in Part IV concerning Rights of Clients in all Programs and Services, Part V regarding General Standards of Care Applicable to all Programs and Services; and Part VI concerning Standards Applicable to all Opioid Treatment Programs of these regulations, an Ambulatory Withdrawal Management with Extended On-Site Monitoring (formerly Ambulatory Detox) program shall adhere to the standards in this section of the regulations.

- 40.1 Level 2-WM is an organized outpatient service, which may be delivered in an office setting, health care, or addiction treatment facility by trained clinicians, who provide medically supervised evaluation, withdrawal management, and referral services and assistance as needed for the beneficiary to gain access to other needed Medicaid SUD or mental health services. Appointments for services are regularly scheduled and under a defined set of physician-approved policies and physician-monitored procedures or clinical protocols.
- 40.2 Level 2-WM services are designed to treat the individual's level of clinical severity to achieve safe and comfortable withdrawal from mood-altering chemicals and to effectively facilitate the individual's entry into ongoing treatment and recovery.
- 40.3 Withdrawal management is conducted on an outpatient basis. It is important for medical and nursing personnel to be readily available to evaluate and confirm that withdrawal management in the less supervised setting is relatively safe.
- 40.4 Level 2-WM services shall have qualified professional 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:
- 40.4.1 A designated prescriber with training and experience in assessing and managing intoxication and withdrawal states must be available on site or for consultation at least 10 hours per week; a physician's assistant (PA), NP, or APRN, licensed as physician extenders, may perform duties designated by a physician within their scope of practice following the DSAMH-approved WM protocol.
- 40.4.2 At least one nurse (NP, RN) must be available on site at least 10 hours per week but at no time serve more than 15 beneficiaries.
- 40.4.3 Licensed practitioners or unlicensed counselors with direct supervision on site; one clinician per 12 individuals.
- 40.4.4 One full-time peer specialist or recovery coach.
- 40.5 One FTE during clinic hours must be dedicated to performing referral arrangements for all individuals served by the facility. This FTE may be a licensed practitioner, unlicensed counselor or certified peer.
- 40.6 The agency shall ensure that each ambulatory withdrawal management program site is certified as an opioid treatment program (OTP) by the federal Substance

Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT), Division of Pharmacologic Therapies (DPT) under 42 CFR Part 8, including meeting all regulatory requirements described therein.

- 40.7 Ambulatory withdrawal management programs may be co-located with another opioid treatment program (OTP) (e.g., Outpatient Opioid Treatment Program, Medically Monitored Inpatient Withdrawal Management Program) in order to maximize efficiencies of services.
- 40.8 Ambulatory withdrawal management programs shall serve individuals who:
 - 40.8.1 Are in need of medication-assisted withdrawal from opioids;
 - 40.8.2 Meet ASAM criteria for service Level 2-WM (ambulatory withdrawal management with extended on-site monitoring);
 - 40.8.3 Do not require an inpatient setting; and
 - 40.8.4 Are not enrolled in another opioid treatment program unless they are continuing a 30-day withdrawal management regime and transferred from an inpatient withdrawal management program.
- 40.9 Medications for opioid withdrawal management in ambulatory settings may include methadone, buprenorphine, and naloxone among others.
- 40.10 The intake screening shall include verification of an applicant's identity, including:
 - 40.10.1 Name;
 - 40.10.2 Address;
 - 40.10.3 Date of birth; and
 - 40.10.4 Photographic identification;
- 40.11 An assessment of clinical services need, including:
 - 40.11.1 A nursing assessment that includes an addiction-focused history conducted at time of admission that is reviewed by a physician to determine need for withdrawal management, eligibility, and appropriateness (proper patient placement) for admission and referral.
 - 40.11.2 Medical examination performed by qualified medical personnel prior to prescribing to determine current physiologic dependence and/or history of dependence on an opiate or opioid substance with DSM-5 criteria, and to include:
 - 40.11.2.1 Qualified medical personnel statement that treatment is medically necessary;
 - 40.11.2.2 Comprehensive DSM-5 diagnosis;
 - 40.11.2.3 Urine drug screens upon admission and as directed by the physicians' orders, and
 - 40.11.2.4 A physical examination by qualified medical personnel that shall include:
 - 40.11.2.4.1 Documentation of the client's general appearance with a focus on the clinical signs and symptoms of dependence;
 - 40.11.2.4.2 Documentation of vital signs;
 - 40.11.2.4.3 A complete medical history;
 - 40.11.2.4.4 The client's family medical history;

- 40.11.2.4.5 A list of all medications currently being taken; and
- 40.11.2.4.6 Determination by qualified medical personnel that ambulatory withdrawal management is medically necessary.
- 40.11.3 Laboratory tests including serology and other tests deemed necessary by the program physician.
- 40.11.4 A biological test for pregnancy for all women of child-bearing age.
- 40.11.5 HIV testing should be encouraged, and conducted with the client's signed consent.
- 40.11.6 An *initial* recovery plan, including a plan for withdrawal management, shall be completed within 24 hours of admission based on the findings of the physical examination and that includes a daily assessment of progress during withdrawal management. The recovery care plan must be:
 - 40.11.6.1 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; and
 - 40.11.6.2 Reviewed by a physician and shall be filed in the individual's record and updated as needed.
 - 40.11.6.3 Inclusive of the individual's documented response to and/or participation in scheduled activities.
- 40.11 The diagnostic assessment shall be initiated within 24 hours of admission and completed with 48 hours of admission or when the client is medically stable.
- 40.12 The *initial* recovery plan shall be completed by clinical staff within 24 hours of admission or when the client is medically stable.
- 40.13 Recovery plan updates/revisions shall occur within seven (7) days of admission, and every seven (7) days thereafter; and more frequently if necessary based upon significant changes in client needs.
- 40.14 Counseling services may be available through the withdrawal management program or may be accessed through affiliation with entities providing outpatient services.
- 40.15 Individual counseling shall include at least one (1) 60-minute counseling session per-week by a qualified Counselor.
- 40.16 Group counseling shall include at least two (2) 90-minute sessions per-week .
- 40.17 The discharge plan shall begin at admission and will be comprehensive and complete at discharge.
- 40.18 In addition to the requirements of these regulations the ambulatory withdrawal management program shall develop policies and procedures that describe:
 - 40.18.1 The program's medical/nursing monitoring schedule including:
 - 40.18.2 Monitoring on the first day to determine the response to withdrawal management medication;
 - 40.18.3 Monitoring of vital signs throughout the withdrawal management process; and
 - 40.18.4 Monitoring of symptom history within the most recent 24

hours;

- 40.19 The program's drug-screening procedure;
- 40.20 The program's ambulatory withdrawal management medication dispensing procedure; and
- 40.21 The program's rules including non-compliance, and discharge procedures, to include:
 - 40.21.1 Administrative withdrawal management medication withdrawal.
- 40.22 The program shall have protocols developed and supported by a physician knowledgeable in addiction medicine setting forth:
- 40.23 A medication policy that complies with these regulations and includes:
 - 40.23.1 Induction protocols and policies for:
 - 40.23.1.1 Day one and day two of opioid withdrawal management; and
 - 40.23.1.2 Day three of opioid withdrawal management and forward;
 - 40.23.2 Induction protocols and policies for all other medications used in withdrawal management;
 - 40.23.3 Stabilization that includes:
 - 40.23.3.1 Documentation and rationale for changes in medication dosage;
 - 40.23.3.2 Average length-of-stay criteria; and
 - 40.23.3.3 Criteria for linkage to outpatient treatment.
 - 40.23.4 Protocols for the decrease and/or discontinuance of withdrawal management medications to include:
 - 40.23.4.1 Protocols for decreasing or discontinuing withdrawal management medications when the client requests;
 - 40.23.4.2 Protocols for decreasing or discontinuing when the program determines that maximum benefit has been achieved; and
 - 40.23.4.3 Protocols for decreasing or discontinuing when being administratively discharged or if the client chooses no further treatment.
 - 40.23.5 The protocol staff should follow to respond to medical complications throughout the withdrawal management process.
 - 40.23.6 Physician orders are required for medical and psychiatric management.

Section 41.0 Outpatient Opioid Treatment Services

In addition to meeting requirements in Part IV concerning Rights of Clients in all Programs and Services; Part V regarding General Standards of Professional Care Applicable to All Programs and Services, and Part VI regarding Standards Applicable to All Opioid Treatment Programs of these regulations, an Outpatient Opioid Treatment program shall adhere to the standards in this section.

- 41.1 The agency shall ensure that each outpatient opioid treatment program site is certified as an opioid treatment program (OTP) by the federal Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT), Division of Pharmacologic Therapies (DPT) under 42 CFR Part 8, including meeting all regulatory requirements described therein.

- 41.2 Outpatient opioid treatment programs shall serve individuals who:
- 41.2.1 Meet DSM-5 criteria for and request medication-assisted treatment for an opioid use disorder;
 - 41.2.2 Meet ASAM criteria for service Level I (outpatient treatment) and);
 - 41.2.3 Are not in need of medically supervised withdrawal management from benzodiazepines, alcohol or other drugs;
 - 41.2.4 Do not require an inpatient setting or hospitalization; and
 - 41.2.5 Are not enrolled in another opioid treatment program.
- 41.3 The agency shall ensure the following are in place:
- 41.3.1 Written agreements, updated annually, with back-up licensed professionals, for the coverage of dispensing and other medical needs if regular personnel are not available;
 - 41.3.2 A contract with a certified laboratory to perform urine drug screens or other approved test and report results directly to the program;
 - 41.3.4 A contract with a qualified vendor to calibrate methadone dispensing equipment and/or lease such equipment to the program;
 - 41.3.5 A contract with a pharmacy to provide liquid bulk methadone, buprenorphine/naloxone in sublingual tablet form, and naltrexone;
 - 41.3.6 A reliable system for confirming the identities of clients before dispensing; and
 - 41.3.7 Written agreements, updated annually, for the use of an alternate OTP program, hospital or other medication assisted treatment site for dispensing during an emergency period.
- 41.4 OTPs shall operate at least 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 operate at least three (3) hours either Saturday or Sunday.
- 41.5 Each OTP shall post medication dispensing and counseling hours in a public place within the facility.
- 41.6 The intake screening shall include verification of an applicant's identity, including:
- 41.6.1 Name, address, and date of birth; and
 - 41.6.2 Photographic identification.
- 41.7 For further identification verification, the program may:
- 41.7.1 Issue a confidential photograph-embedded identification card; and/or;
 - 41.7.2 Utilize electronic biological identification techniques (e.g., retina or fingerprint scans).
- 41.8 Additional screening that may occur after admission shall include:
- 41.8.1 Checking for dual enrollment in an OTP with the Division's Eligibility and Enrollment Unit (EEU); and
 - 41.8.2 A program physician querying the State Prescription Monitoring Program to verify reported client prescription for controlled medications.
- 41.9 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. Such exceptions shall be noted in the client's record;

- 41.10 Special admission populations (where the absence of physiological dependence shall not be an exclusion criterion with a clinically justifiable admission) shall include:
- 41.10.1 Persons recently released from a penal institution (within six (6) months after release);
 - 41.10.2 Pregnant clients (program physician shall certify pregnancy);
 - 41.10.3 Previously treated clients (up to two (2) years after discharge); and
 - 41.10.4 A client re-admitted to the same program within 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.
- 41.11 The clinical assessment shall include:
- 41.11.1 Medical examination performed by qualified medical personnel to determine current physiologic dependence and/or history of dependence on opiate or opioid substance(s) prior to prescribing opioid treatment medications;
 - 41.11.2 Comprehensive DSM-5 diagnosis;
 - 41.11.3 A physical examination by qualified medical personnel Per 42 CFR Part 8, including a fully documented physical evaluation by a program physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician is completed prior to admission. The full medical examination, including the results of serology and other tests, must be completed within 14 days following admission to an OTP that shall include:
 - 41.11.3.1 Documentation of the client's general appearance with a focus on the clinical signs and symptoms of dependence
 - 41.11.3.2 Documentation of vital signs;
 - 41.11.3.3 A complete medical history;
 - 41.11.3.4 The client's family medical history;
 - 41.11.3.5 A list of all medications currently being taken and/or prescribed; and
 - 41.11.3.6 Determination that opioid treatment is medically necessary.
 - 41.11.4 Laboratory tests including serology and other tests deemed necessary by the program physician.
 - 41.11.5 A biological test for pregnancy for all women of child-bearing age.
 - 41.11.6 HIV testing should be encouraged, and conducted with the client's signed consent.
- 41.13 A medical care plan shall be completed within 24 hours of admission based on the findings of the physical examination.
- 41.14 The diagnostic assessment shall be completed within 24 hours of admission in collaboration with the client.
- 41.15 The initial recovery plan shall be completed by clinical staff within 72 hours of admission.
- 41.16 Recovery plan updates/revisions shall occur within 72 hours of admission, and every 90 days thereafter; and more frequently if necessary based upon significant changes in client needs.

- 41.17 Individual and group counseling frequency should be based on each client's assessed needs.
- 41.18 The discharge plan shall be begun at admission.
- 41.19 The agency shall develop policies and procedures for the OTP that include requiring that:
- 41.20.1 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;
 - 41.20.2 Initial doses of methadone shall not exceed 30mg and the total dose for the first 24 hours shall not exceed 40mg, unless the program physician documents in the client's record that 40mg did not adequately suppress opiate abstinence symptoms;
 - 41.20.3 Clients transferred from another OTP program may receive their daily dose as ordered by the transferring physician after medical personnel verify the dose to the receiving OTP program;
 - 41.20.4 Emergency, or courtesy dosing shall be permitted without screening and assessment procedures being completed, with approval from the medical director.
 - 41.20.5 Only a licensed professional authorized by law may administer or dispense opioid treatment medication;
 - 41.20.6 Medications for opioid treatment shall include methadone and buprenorphine, and others approved by the federal Food and Drug Administration (FDA) for opioid treatment;
 - 41.20.7 Ingestion shall be observed and verified by the personnel authorized to administer the opioid treatment medication;
 - 41.20.8 There shall be only one (1) client in the immediate dispensing area at a time;
 - 41.20.9 OTP programs shall dispense methadone in liquid form, and otherwise in accordance with Federal and State laws and regulations in containers conforming to 42 CFR Part 8 Section 12.(i)(5);
 - 41.20.10 An exception to use of liquid methadone shall be in the case of a client approved by the program for air travel, if approved by the medical director.
 - 41.20.11 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; and
 - 41.20.12 The medical director shall ensure that significant adverse drug reactions are reported to the FDA and to the manufacturer in a manner that does not violate the client's confidentiality.
- 41.21 Treatment program decisions on dispensing unsupervised (i.e., 'take-home') medications shall be determined by the program physician. The program physician shall consider the following criteria to determine whether a client is responsible in handling medication for unsupervised use:
- 41.21.1 Regularity of program attendance;
 - 41.21.2 Absence of recent use of drugs, including alcohol;
 - 41.21.3 Regularity of OTP program attendance;

- 41.21.4 Absence of serious behavioral problems at the OTP program;
- 41.21.5 Absence of known recent criminal activity (e.g. drug and drug-related arrests, etc.);
- 41.21.6 Progress in meeting recovery plan goals;
- 41.21.7 Length of time in treatment;
- 41.21.8 Responsibility in the handling, and plan for the safe storage, of take-home opioid treatment medications; and
- 41.21.9 Stability of the client's home environment and social relationships.
- 41.22 When it is determined that a client is responsible in handling opioid treatment medications, the Federal Regulations (42 CFR Part 8) for take-home privileges shall be applied, unless these regulations, or a Director's administrative directive, or the judgment of the SOTA are more restrictive.
- 41.23 OTP programs shall maintain current procedures adequate to prevent and identify the theft or diversion of take-home medications, including:
 - 41.23.1 Labeling containers with the OTP's name, address, and telephone number; and
 - 41.23.2 Requiring clients to come to the OTP program on a randomly scheduled basis for drug testing and checking the amount of take-home medication used to that point.
- 41.24 Programs shall also ensure that take-home supplies are packaged in a manner designed to reduce the risk of accidental ingestion, including child-proof containers.
- 41.25 The program physician will determine if a client's conduct warrants revocation or suspension of take-home privileges.
- 41.26 Documentation of the rationale for revoking, suspending or reducing take-home privileges will be entered into the client's record by the program physician.
- 41.27 Using their judgment the program physician:
 - 41.27.1 May approve a reduced attendance schedule if a client has a physical disability that interferes with his or her ability to conform to the applicable mandatory attendance schedule.
 - 41.27.2 When 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.
 - 41.27.3 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.
 - 41.27.4 Any client who transfers from an 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.
- 41.27.5 Any exceptions in these regulations must be reported to the SOTA, and an electronic exception request form (SMA-168) must be submitted to SAMHSA in accordance with 42 CFR Part 8.
- 41.28 Voluntary medical withdrawal from opioid treatment medication shall include:
- 41.28.1 A request signed and dated by the client, for voluntary medication withdrawal.
- 41.28.2 Documentation of the program physician's rationale for initiation of withdrawal.
- 41.28.3 Documentation of the program physician's rationale for continuing the withdrawal if there is any change in the program physician's orders.
- 41.28.4 Documentation signed and dated by the client that the withdrawal will be discontinued and maintenance resumed at the client's request.
- 41.28.5 A biological test for pregnancy for all women of child-bearing age prior to the initiation of withdrawal.
- 41.28.6 Revision of the recovery plan with an increase in counseling and other support services in relation to medication dosage changes.
- 41.28.7 Provisions for continuing care after the last dose of opioid treatment medication.
- 41.29 Withdrawal against medical advice shall require:
- 41.29.1 Documentation of all efforts taken by staff members to discourage initiation and continuation of withdrawal against medical advice.
- 41.29.2 Documentation of the reasons the client is seeking withdrawal against medical advice.
- 41.29.3 Agencies shall have written policies and procedures defining the criteria and justification for initiating a client's involuntary, or administrative, withdrawal from opioid treatment medication, including for non-payment of fees (i.e., 'fee-tox').
- 41.29.4 Involuntary withdrawal from an opioid treatment medication shall be conducted in accordance with a dosage reduction schedule prescribed by the physician; and ensure that:
- 41.29.4.1 Clients being involuntarily discharged shall be referred to other treatment, as clinically indicated.
- 41.29.4.2 OTP programs shall document the reasons for initiation of involuntarily withdrawal in the client's record.
- 41.29.4.3 Prior to the beginning of involuntary withdrawal, efforts must be documented regarding referral or transfer of the client to a suitable, alternative treatment program.
- 41.30 Documentation during withdrawal shall include:
- 41.30.1 Documentation by the physician of the schedule for withdrawal and any changes made to the schedule by the physician during the withdrawal.
- 41.30.2 Counseling designed to promote the continuation of services following medical withdrawal.

Section 42.0 Clinically Managed Low-Intensity Residential Treatment (ASAM Level 3.1)

In addition to meeting standards in Part IV concerning Rights of Clients in all Programs and Services, Part V regarding General Standards of Professional Care Applicable to all Programs and Services, and Part VI regarding Standards Applicable to all Residential/ Inpatient Programs, agencies operating Clinically Managed Low-Intensity Residential Treatment programs shall meet the standards within this section. Level 3.1 is a 24-hour supportive living environment whereas the other Level 3 programs/levels are 24-hour treatment settings. Level 3.1 is not intended to describe or include sober houses, boarding houses or group residences where treatment services are not provided. Care delivered by Level 3.1 programs includes a clinical services component and a recovery residence component. An example of a Level 3.1 program is a halfway house, or other Supportive Living Environment (SLE) with 24-hour staff and close integration with clinical services.

- 42.1 Clinically managed, low-intensity residential treatment programs (i.e., halfway houses) shall accept clients who:
- 42.1.1 Meet ASAM criteria for Level 3.1 services;
 - 42.1.2 Do not require a higher level or intensity of residential or inpatient treatment or hospitalization;
 - 42.1.3 Are referred for continuing care from a higher level of care, including residential or inpatient treatment or withdrawal management;
 - 42.1.4 Do not require medical services for acute intoxication or withdrawal from alcohol or other drugs;
 - 42.1.5 Are medically and psychiatrically stable and capable of managing self-administration of their medications;
 - 42.1.6 Are not being referred primarily due to the need for stable housing; and/or
 - 42.1.7 Are referred for transitional care following a period of detainment or incarceration in an institutional or community correctional facility AND have received treatment for a substance use disorder within the previous six (6) months AND have been actively engaged in recovery support activities (e.g., AA/NA, peer recovery supports, etc.) AND have been assessed by the Division's TASC program AND have been authorized by the Division's EEU for placement.
- 42.2 In addition to the requirements applicable to in other sections of these regulations, Clinically Managed Low-Intensity Residential Treatment programs shall provide:
- 42.2.1 Services may include individual, group and family therapy; medication management and medication education; mental health evaluation and treatment; vocational rehabilitation and job placement; and either introductory or remedial life skills workshops. Level 3.1 programs should have the ability to arrange for pharmacotherapy for psychiatric or anti-addiction medications.
 - 42.2.1 Meals in accordance with these regulations, except residents may

- prepare their own meals, individually or communally.
- 42.2.2 Housing in accordance with these regulations, with additional policies and procedures for regular supervised and unsupervised access to the community.
- 42.2.3 Physical examination by qualified medical personnel within 72 hours of admission unless the client has had a physical examination completed by qualified medical personnel within 90 days prior to admission.
- 42.2.4 Within 72 hours of admission, a biopsychosocial assessment in accordance with these regulations.
- 42.3 Within 72 hours of admission, a recovery plan in accordance with these regulations that reflects case management conducted by on-site staff; coordination of related addiction treatment, health care, mental health, and social, vocational or housing services (provided concurrently); and the integration of services at this and other levels of care.
- 42.4 Recovery plan review/revision in accordance with these regulations as needed based on changes in functioning for each client and, at a minimum, every 90 days.
- 42.5 Telephone or in-person consultation with a physician and emergency services, available 24 hours a day, 7 days a week.
- 42.6 A minimum of five (5) hours per-week of clinical services including: individual, group and/or family counseling with a qualified counselor; and psycho-educational groups.
- 42.7 A minimum of five (5) hours per-week of on- and/or off-site peer-based recovery support services that may include: peer-run self-help groups, recovery support meetings, one-on-one recovery coaching, telephonic and similar supports.
- 42.8 Recovery-based programming must be offered seven (7) days per week.
- 42.9 Off-site Religious Services must be offered at least one (1) day per week, including Sundays.
- 42.10 Case management services provided as needed.
- 42.11 Availability of 24-hour, on-call medical and psychiatric consultation by professionals experienced in addiction treatment.
- 42.12 The program shall operate 24 hours per-day, seven (7) days per-week.
- 42.13 The program shall have written affiliation agreements for the provision of services not provided in-house.
- 42.14 When clients are present, there shall be at least one (1) staff on duty at all times.
- 42.15 A counselor shall be available to clients 24 hours per-day, seven (7) days per-week.
- 42.16 The agency shall have policies and procedures addressing the following:
- 42.16.1 Client screening;
- 42.16.2 Room searches;
- 42.16.3 Other measures that ensure a substance-free environment and safety for all clients;
- 42.16.4 Transportation of clients to off-site services and activities;
- 42.16.5 Client-owned vehicles on grounds; and

- 42.16.6 Client in-house chore and work responsibilities, and opportunities for paid positions.
- 42.17 The agency shall have written agreements with community-based specialty service agencies and providers including, but not limited to the following:
 - 42.17.1 Psychiatric care including medication management;
 - 42.17.2 Primary care health services;
 - 42.17.3 Vocational training and/or rehabilitation;
 - 42.17.4 Community supervision agencies (e.g., probation, parole); and
 - 42.17.5 Adult and continuing education services.
- 42.18 The focus of discharge planning shall be on assisting the resident with the following, among others:
 - 42.18.1 Locating permanent safe and sober housing;
 - 42.18.2 Obtaining gainful employment and/or pursuing continuing education or vocational training;
 - 42.18.3 Engaging in recovery supports aimed toward attaining sustained recovery in the community;
 - 42.18.4 Participating in continuing treatment or counseling as needed;
 - 42.18.5 Connecting with a positive, growth-supportive and recovery-oriented social support network;
 - 42.18.6 Locating and connecting with rehabilitative services in the community, as needed;
 - 42.18.7 Learning and practicing independent living skills;
 - 42.18.8 Achieving and maintaining personal wellness (e.g., physical fitness, healthy nutrition, tobacco cessation, etc.)

Section 43.0 Clinically Managed High-Intensity Residential Treatment (ASAM Level 3.5)

In addition to meeting standards in Part IV concerning Rights of Clients in all Programs and Services, Part V regarding General Standards of Care Applicable to all Programs and Services, and Part VI regarding Standards Applicable to all Residential/Inpatient Programs, agencies operating Clinically Managed High-Intensity Residential Treatment programs shall meet the standards within this section. Level 3.5 programs are designed to serve individuals who, because of specific functional limitations, need safe and stable living environments in order to develop and/or demonstrate sufficient recovery skills so that they do not immediately relapse or continue to use in an imminently dangerous manner upon transfer to a less intensive level of care. Their multidimensional needs are of such severity that they cannot safely be treated in less intensive levels of care.

- 43.1 Clinically managed, high-intensity residential treatment programs shall accept clients who have been pre-authorized by the Division's EEU for placement, and:
 - 43.1.1 Meet ASAM criteria for Level 3.5 residential services;
 - 43.1.2 Do not require a higher level of care (i.e., inpatient treatment or hospitalization);
 - 43.1.3 Are referred for continuing care from a higher level of care, including inpatient treatment or withdrawal management;
 - 43.1.4 Are referred from a lower level of care due to the need for more intensive

- or restrictive treatment;
- 43.1.5 Do not require medical services for acute intoxication or withdrawal from alcohol or other drugs;
 - 43.1.6 Are medically and psychiatrically stable and capable of managing self-administration of their medications;
 - 43.1.7 Are not being referred primarily due to the need for stable housing; and/or
 - 43.1.8 Are referred for extended residential treatment and rehabilitation following a period of detainment or incarceration in an institutional or community correctional facility AND have received treatment for a substance use disorder within the previous six (6) months AND have been actively engaged in recovery support activities (e.g., AA/NA, peer recovery supports, etc.) if having completed such treatment AND have been assessed by the Division's TASC program.
- 43.2 The program shall operate 24 hours per-day, seven (7) days per-week.
 - 43.3 The program shall provide recovery-based programming seven (7) days per week.
 - 43.4 Off-site religious services must be offered at least one (1) day per week, including Sundays.
 - 43.5 The program shall have a modified therapeutic milieu that includes behavioral management, socialization skills, life skills and pre-vocational training components.
 - 43.6 The program shall have written affiliation agreements for the provision of services required by the recovery plan in these regulations, when these services are not provided in-house.
 - 43.7 In addition to the requirements applicable to in other sections of these regulations, clinically managed high-intensity residential treatment programs shall provide:
 - 43.7.1 Meals in accordance with these regulations, except residents may assist staff in preparation of the client population's meals.
 - 43.7.2 Housing in accordance with these regulations, with additional policies and procedures for supervised access to the community.
 - 43.7.3 Physical examination by qualified medical personnel within 24 hours of admission unless the client has had a physical examination completed by qualified medical personnel within 90 days prior to admission.
 - 43.7.4 Within 48 hours of admission, a biopsychosocial assessment in accordance with these regulations.
 - 43.7.5 Within 72 hours of admission, a recovery plan in accordance with these regulations that reflects case management conducted by on-site staff; coordination of related addiction treatment, healthcare, mental health, and social, vocational or housing services (provided concurrently); and the integration of services at this and other levels of care.
 - 43.7.6 Recovery plan review/revision in accordance with these regulations as needed based on changes in functioning for each client and, at a minimum, every 30 days after completion of the plan.
 - 43.8 The following services shall be provided as needed:

- 43.8.1 Medical evaluation and consultation by a licensed physician, as needed. Telephone or in-person consultation with a physician, or a physician assistant or nurse practitioner in states where they are licensed as physician extenders and may perform the duties designated here for a physician; emergency services, available 24 hours a day, 7 days a week and arranged medical, psychiatric, psychological, laboratory and toxicology services, as appropriate to the severity and urgency of the patient's condition.
- 43.8.2 Emergency medical and hospital services available at a licensed hospital, as needed.
- 43.8.3 A range of evidenced-based cognitive, behavioral and other therapies administered on an individual and group basis, medication education and management, addiction pharmacotherapy, educational skill building groups, and occupational or recreational activities, adapted to the patient's developmental stage and level of comprehension, understanding and physical abilities.
- 43.9 Level 3.5 residential programs offer 24-hour treatment staff with at least 30 hours per week of a combination of clinical and recovery-focused services specifically focused on individuals who have significant social and psychological problems.
- 43.10 At least 10 of the 30 hours are to include individual, group, and/or family counseling.
- 43.11 A minimum of ten (10) hours of the 30 hours per-week can be of on- and/or off-site peer-based recovery support services that may include: peer-run self-help groups, peer counseling groups, recovery support meetings, one-on-one recovery coaching, telephonic and similar supports.
 - 43.11.1 Case management and follow up services provided as needed.
 - 43.11.2 Availability of 24-hour, on-call medical and psychiatric consultation.
- 43.12 When clients are present, there shall be at least two (2) employed staff on duty at all times, and three (3) in co-ed facilities.
- 43.13 A counselor shall on site and available to clients 24 hours per-day, seven (7) days per-week.
- 43.14 Staff to client ratio shall be no less than 1:15 between the hours of 10 PM and 6 AM. At all other times, staff to client ratio shall be no less than 2:15.
- 43.15 A licensed nurse or physician's assistant shall be on-site at least two (2) days per-week for a minimum total of eight (8) hours per week.
- 43.16 A program physician shall be available on-site at least four (4) hours per-week.
- 43.17 The agency shall have policies and procedures addressing the following:
 - 43.17.1 Client screening, room searches and the like that ensure a substance-free environment and safety for all clients.
 - 43.17.2 Transportation of clients to off-site services and activities.
 - 43.17.3 Client-owned vehicles on grounds.
 - 43.17.4 Client in-house chores.
 - 43.17.5 Allowing clients to perform structured work responsibilities that would not otherwise be done by paid staff, as defined in vocational training curriculum and guidelines, and performed under experienced staff supervision.

- 43.18 Agreements with community-based specialty service agencies and providers including, but not limited to the following:
 - 43.18.1 Psychiatric care including medication management;
 - 43.18.2 Primary care health services;
 - 43.18.3 Vocational training and/or rehabilitation;
 - 43.18.4 Community supervision agencies (e.g., probation, parole); and
 - 43.18.5 Adult and continuing education services.
- 43.19 The focus of discharge planning shall be on assisting the resident with the following, among others:
 - 43.19.1 Locating permanent safe and sober housing;
 - 43.19.2 Obtaining gainful employment and/or pursuing continuing education or vocational training;
 - 43.19.3 Engaging in recovery supports aimed toward attaining sustained recovery in the community;
 - 43.19.4 Participating in continuing treatment or counseling as needed;
 - 43.19.5 Connecting with a positive, growth-supportive and recovery-oriented social support network;
 - 43.19.6 Locating and connecting with rehabilitative services in the community, as needed;
 - 43.19.7 Learning and practicing independent living skills; and
 - 43.19.8 Achieving and maintaining personal wellness (e.g., physical fitness, healthy nutrition, tobacco cessation, etc.)

Section 44.0 Clinically Managed Residential Withdrawal Management (ASAM Level 3.2-WM)

In addition to meeting standards in Part IV concerning Rights of Clients in all Programs and Services, Part V regarding General Standards of Care Applicable to all Programs and Services, and Part VI regarding Standards Applicable to all Residential/ Inpatient Programs, agencies operating Clinically Managed Residential Withdrawal management (formerly Social Detox) programs shall meet the standards within this section.

- 44.1 Residential programs provided in an organized, residential, non-medical setting delivered by an appropriately trained staff that provides safe, 24-hour medication monitoring observation and support in a supervised environment for a person served to achieve initial recovery from the effects of alcohol and/or other drugs. The program emphasis is on peer and social support, not medical and nursing care.
- 44.2 Since Level 3.2-WM is managed by clinicians, not medical or nursing staff, protocols are in place should a patient's condition deteriorate and appear to need medical or nursing interventions. These protocols are used to determine the nature of the medical or nursing interventions that may be required. Protocols include under what conditions nursing and physician care is warranted and/or when transfer to a medically monitored facility or an acute care hospital is necessary. The protocols are developed and supported by a physician knowledgeable in addiction medicine.

- 44.3 Residential withdrawal management programs shall serve individuals who:
 - 44.3.1 Meet ASAM criteria for service Level 3.2-WM (clinically managed residential withdrawal management) services;
 - 44.3.2 Are intoxicated or in mild-to-moderate withdrawal from opiates, alcohol, or other drugs, but do not require urgent medical attention or direct medical observation during their stay;
 - 44.3.3 Do not require an inpatient setting or hospitalization for management of withdrawal, or for other acute medical or psychiatric conditions; and
 - 44.3.4 Are not in need of medication-assisted withdrawal from opioids or other drugs.
- 44.4 Residential withdrawal management programs shall operate 24 hours per-day.
- 44.5 In addition to affiliation with other levels of care, the agency or program shall have written agreements with:
 - 44.5.1 Local medical personnel (i.e., nurse, physician, psychiatrist) to provide on-site and telephonic or video-presence evaluation and consultation 24 hours per-day;
 - 44.5.2 Emergency medical technicians; and
 - 44.5.3 Hospital and ambulance services.
- 44.6 Urine drug screens are required upon admission and as directed by the withdrawal management recovery plan.
- 44.7 Screening shall be conducted by a staff person who is trained and experienced in recognizing signs and symptoms of withdrawal and who shall administer any of the following, as appropriate:
 - 44.7.1 Clinical Institute Withdrawal Assessment (CIWA-AR)
 - 44.7.2 Clinical Opiate Withdrawal Scale (COWS)
 - 44.7.3 ASAM placement criteria
 - 44.7.4 Mental status examination
 - 44.7.5 Screening to identify signs and symptoms of intoxication, impairment and withdrawal, including use of a breathalyzer
 - 44.7.6 Self or significant other history of recent drug and alcohol use, and
 - 44.7.7 An inventory of prescription and over-the-counter medication currently being used.
- 44.8 Service expectations shall include:
 - 44.8.1 A bio-physical screening including at a minimum, vital signs, withdrawal management rating scale, and fluid intake conducted by trained staff at admission or documentation of a physical examination within the last three (3) months;
 - 44.8.2 Ongoing monitoring of safety, physical and mental condition as needed, with licensed medical consultation available by telephone, video-presence, or in-person, 24 hours per-day;
 - 44.8.3 Observation of medication self-administration that is documented;
 - 44.8.4 A comprehensive nursing assessment at admission, including an addiction-focused history about the individual to provide a clear understanding of the individual's present status. If self-administered

withdrawal management medications are to be used, a physical examination by a physician, physician assistant, or nurse practitioner should be made at time of admission. Assessment of addiction-focused history to be reviewed with a physician during the admission process.

- 44.8.5 A diagnostic assessment completed within 24 hours of admission which substantiates appropriate patient placement reviewed and signed by a qualified professional;
- 44.8.6 Development of an *initial* individualized interdisciplinary treatment/recovery care plan within 24 hours in collaboration with the individual to address treatment priorities identified in ASAM Dimensions 2 through 6; and a comprehensive treatment/recovery plan within 72 hours if participant is still in the service;
- 44.8.7 Additional updates to the treatment/recovery plan as indicated;
- 44.8.8 Daily assessment of individual progress through withdrawal management and any treatment changes;
- 44.8.9 Motivational interviewing (MI) to engage and encourage clients to enroll in continuing treatment at a level needed based upon ASAM criteria;
- 44.8.10 Peer recovery specialist support and counseling, daily;
- 44.8.11 Interventions shall include a variety of psycho-educational sessions for individuals addressing substance use and mental disorders and their treatment;
- 44.8.12 Individual client participation in counseling activities shall be based on their bio-physical condition;
- 44.8.13 An initial discharge plan must be completed within 24 hours of admission, and a comprehensive discharge plan at discharge developed in concert with the individual which shall include:
- 44.8.14 Specific referrals for continuing treatment and assistance as needed for the beneficiary to gain access to other needed Medicaid SUD or mental health services.
- 44.8.15 A personal wellness and recovery plan; and
- 44.8.16 Assisting the client to establish social recovery supports in the community.

Staffing

- 44.9 Level 3.2-WM withdrawal management programs are staffed by appropriately credentialed personnel who are trained and competent to implement physician-approved protocols for patient observation and supervision, determination of appropriate level of care, and facilitation of the patient's transition to continuing care. Programs that supervise self-administered medications have appropriately licensed or credentialed staff and policies and procedures in accordance with state and federal law.
- 44.10 Staffing shall include, at a minimum:
 - 44.10.1 All staff shall be thoroughly trained and experienced in recognizing signs and symptoms of alcohol and other drug intoxication and withdrawal, as well as the appropriate treatment and monitoring of those conditions and how to facilitate entry into ongoing care, mental status and symptoms of potential distress requiring various levels of intervention by medical and/or emergency personnel;

- 44.10.2 The facility shall be directed by a clinical who holds a license;
- 44.10.3 There shall be certified addiction counselors in sufficient numbers to provide case management and counseling services;
- 44.10.4 There shall be at least one (1) Peer Recovery Coach on duty and awake 24 hours per-day;

Documentation

- 44.11 Documentation standards of Level 3.2-WM programs include progress notes in the patient record that clearly reflect implementation of the withdrawal management and recovery plan and the client's response to treatment, as well as subsequent amendments to the plan. Withdrawal rating scale tables and flow sheets (which may include tabulation of vital signs) are used as needed.
- 44.12 The clinical record shall contain all information as required in these regulations.

Section 45.0 Medically Monitored Inpatient Withdrawal Management (ASAM Level 3.7-WM)

- 45.1 Level 3.7-WM: Medically Monitored Inpatient Withdrawal Management is an organized service delivered by medical and nursing professionals, which provides for 24-hour evaluation and withdrawal management in a permanent facility with inpatient beds. Services are delivered under a defined set of physician-approved policies and physician-monitored procedures or clinical protocols.
- 45.2 In addition to meeting standards in Part IV concerning Rights of Clients in all Programs and Services, Part V regarding General Standards of Care Applicable to all Programs and Services, and Part VI regarding Standards Applicable to all Residential/ Inpatient Programs, agencies operating Medically Monitored Inpatient Withdrawal management (Medical Detox) programs shall meet the standards within this section.
- 45.3 The agency shall ensure that each medical withdrawal management program site is certified as an opioid treatment program (OTP) by the federal Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT), Division of Pharmacologic Therapies (DPT) under 42 CFR Part 8, including meeting all regulatory requirements described therein, including any State or Federal requirements not referenced.
- 45.4 Medically monitored inpatient withdrawal management within a residential setting is an organized service delivered by medical and nursing professionals, which provide for 24-hour medically-supervised evaluation under a defined set of physician-approved policies and physician-monitored procedures or clinical protocols.
- 45.5 Medical withdrawal management programs shall ideally be co-located with: ambulatory withdrawal management; and/or 23-hour substance-related observation services; and/or clinically-managed high-intensity residential treatment (ASAM Level 3.5) program(s).
- 45.6 The agency shall have policies and procedures and protocols that maximize the efficient use of withdrawal management beds and expedite discharges that will result in high connect-to-treatment rates and low recidivism rates. Specifically, medical withdrawal management services shall aim toward:
- 45.6.1 Providing urgent evaluation and stabilization of the individual including continuous monitoring of the clients vital signs in accordance with

- medical order/protocol;
- 45.6.2 Utilizing effective medications to mitigate withdrawal symptoms and distress;
 - 45.6.3 Maximizing client motivation to seek treatment at the necessary level-of-care;
 - 45.6.4 Seeking residential treatment for the client, if needed and medically justified;
 - 45.6.5 Actively facilitating direct transfer to a treatment facility;
 - 45.6.6 Encouraging clients with opioid use disorder of moderate-to-high severity and chronicity to preferably prepare for, and enroll in, an outpatient opioid treatment program, or
 - 45.6.6.1 Physician's office-based buprenorphine/naloxone treatment service; or
 - 45.6.6.2 Minimally, engaging and enrolling the client in an extended (i.e., 30-day) withdrawal management protocol with direct transfer to an ambulatory detox program for completion of medication taper.
- 45.7 Medical withdrawal management programs shall operate 24 hours per-day, seven (7) days per-week and shall:
- 45.7.1 Accept applicants who present for admission 24 hours per-day;
 - 45.7.2 Have access to a physician by telephone 24 hours per-day (a designated medical director knowledgeable in addiction medicine, an addiction 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). A physician must be available to assess the client within 24 hours of admission (or earlier if medically necessary) and is available to provide on-site monitoring of care and further evaluation on a daily basis;
 - 45.7.3 Have a psychiatrist, psychiatric NP, or APRN on site at least 15 hours/week per 15 residents to assess the individual 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.
 - 45.7.4 Primary care/physical health physician (or physician extender) on site at least 15 hours/week for 15 residents.
 - 45.6.5 Have at least one (1) nurse (RN or LPN) per 15 residents on site present and awake at all times with an RN supervisor or NP on call;
 - 45.6.6 Have at least one (1) licensed practitioner or unlicensed counselor awake at all times with direct supervision on site during days and evenings per 15 residents;
 - 45.6.7 One peer recovery coach per 15 residents is on site during days and evenings.
 - 45.6.8 One behavioral health technician is on site and awake at all times per 15 residents.
 - 45.6.9 One FTE during clinic hours dedicated to performing referral arrangements for all individuals served by the facility. This FTE may be a licensed practitioner, unlicensed counselor, or certified peer; and

- 45.6.10 Have continuous access to emergency medical personnel through written agreement with an area medical facility or hospital.
- 45.7 Medical withdrawal management programs shall serve individuals who:
- 45.7.6 Meet ASAM criteria for Level 3.7-WM medically monitored inpatient withdrawal management services;
- 45.7.7 Are in need of urgent medical services for supervised withdrawal from opiates, alcohol or other drugs, and to ensure safety;
- 45.7.8 Are not in need of hospitalization for acute medical and/or psychiatric conditions;
- 45.7.9 Present with symptoms of intoxication, impairment or withdrawal AND either:
- 45.7.9.1 Present with impaired ability to minimally care for themselves due to intoxication, or
- 45.7.9.2 Lack current supportive, safe environment and therefore are at high risk of continued use of drugs or alcohol, or
- 45.7.9.3 Is at risk of harm to self or others as a result of intoxication, impairment or withdrawal.
- 45.8 Screening shall be conducted by a licensed nurse who shall administer the following, as appropriate:
- 45.8.1 Clinical Institute Withdrawal Assessment (CIWA-AR)
- 45.8.2 Clinical Opiate Withdrawal Scale (COWS)
- 45.8.3 ASAM placement criteria
- 45.8.4 Mental status examination
- 45.8.5 Medical screening to identify signs and symptoms of intoxication, impairment and withdrawal, including breathalyzer
- 45.8.6 Brief, self or significant other history of recent drug and alcohol use, and prescription and over-the-counter medication consumption.
- 45.8.7 Admission assessment by qualified medical personnel or a licensed nurse prior to admission to determine the need for inpatient withdrawal management based upon ASAM and preliminary DSM-5 diagnosis.
- 45.8.8 Admission eligibility may be initially determined by licensed nursing staff based upon screening protocols, but a QMP must authorize the admission.
- 45.8.9 Initially, authorization may be performed via telephone or videoconference, resulting in an admission;
- 45.8.10 Initial authorization shall be following within 24 hours by a QMP making a final authorization and diagnosis based upon face-to-face evaluation with the client.
- 45.9 There shall be no dispensing or administration of prescription or non-prescription medications until qualified medical personnel have either examined the client, or been consulted by program staff.
- 45.10 An exception shall be the immediate provision of nicotine replacement therapy (NRT) (e.g., patch and/or gum), unless refused by any nicotine-dependent client and documented in the client record.

- 45.11 Urine drug screens are required upon admission and as directed by the recovery plan.
- 45.12 A complete medical history and physical examination shall be conducted by qualified medical personnel within 24 hours of admission.
- 45.13 A medical care plan shall be completed within 24 hours of admission based on the findings of the physical examination including a brief screening to identify:
- 45.13.1 Motivation for treatment;
 - 45.13.2 Relapse potential; and
 - 45.13.3 Recovery environment at discharge.
- 45.14 A full DSM-5 diagnosis shall be completed by licensed staff within 48 hours of admission.
- 45.15 A recovery plan shall be initiated within 24 hours of admission and completed within 72 hours which includes problem identification in Dimensions 2 through 6 and development of treatment goals and measurable treatment objectives and activities designed to meet those objectives in collaboration with the client and in accordance with these regulations:
- 45.16 If participant is still in the service, additional updates should be made to the treatment/recovery plan as indicated.
- 45.17 For those clients not medically restricted, individual counseling that shall include at least one (1) 15-minute counseling contact per-day with a Counselor.
- 45.18 Group counseling that shall include at least one (1) 60-minute counseling session per-day with a Counselor.
- 45.19 Emergency medical and hospital services shall be available at a licensed hospital, as needed.
- 45.20 The program shall have protocols developed and supported by a program physician knowledgeable in addiction medicine setting forth:
- 45.20.1 The protocol staff should respond to medical complications throughout the withdrawal management process; and the circumstances under which emergency medical intervention is required.
- 45.21 The program shall have written affiliation agreements for the provision of services required by this section, when those services are not provided in-house.
- 45.22 An initial discharge plan must be developed within 24 hours of admission, and comprehensive discharge plan at discharge.
- 45.23 Referral and assistance as needed for the beneficiary to gain access to other needed Medicaid SUD or mental health services.
- 45.24 Upon admission, the program shall record:
- 45.24.1 Client's blood pressure;
 - 45.24.2 Client's pulse;
 - 45.24.3 Client's respiration;
 - 45.24.4 Presence of bruises, lacerations, cuts or wounds;
 - 45.24.5 Any medications carried by the client or found on the client's person; and
 - 45.24.6 At a frequency prescribed by qualified medical personnel, but no less than three (3) times in the first eight (8) hours after admission, the client's:

- 45.24.6.1 Blood pressure;
- 45.24.6.2 Pulse;
- 45.24.6.3 Respiration;
- 45.24.6.4 Type and amount of fluid intake;
- 45.24.6.5 Physical state, including the presence of tremors, ataxia, excessive perspiration, restlessness or sleep disturbances;
- 45.24.6.6 Mental state, including the presence of confusion, hallucinations, and orientation to person, place and time; and
- 45.24.6.7 Emotional state, including the presence of anxiety or depression.

DRAFT