RULES AND REGULATIONS

FOR THE

LICENSING OF

SUBSTANCE ABUSE FACILITIES

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

Department of Mental Health,
Retardation and Hospitals

March 2002

INTRODUCTION

These Rules and Regulations for Licensing Substance Abuse Facilities are promulgated pursuant to the authority conferred in R.I. Gen. Laws 40.1-1-13(11) and are established for the purpose of defining the minimum standards for licensed substance abuse facilities in Rhode Island.

Pursuant to the provisions of R.I. Gen. Laws 42-35-3, the following were given consideration in adopting these regulations: (a) alternative approaches to the regulations; (b) duplication or overlap with other state regulations; and (c) significant economic impact on small business or any city or town. No alternative approach was identified; nor was any duplication or overlap identified. The protection of the health, safety and welfare of the public necessitates the adoption of the regulations despite any economic impact which may be incurred as the result of the adoption of these regulations.

These rules and regulations shall supersede any previous rules and regulations regarding the licensing of substance abuse facilities promulgated by the Department of Mental Health, Retardation and Hospitals or any other State agency filed with the Secretary of State.

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PART I *LICENSING PROCEDURES AND DEFINITIONS*

Section 1.0 *Definitions*

Wherever used in these rules and regulations, the following terms shall be construed as follows:

1.1 ***"Aftercare"*** means post-treatment activities designed to maintain and enhance recovery

1.2 ***"ASAM-PPC"***, means the American Society of Addiction Medicine-Patient Placement Criteria for the Treatment of Substance-Related Disorders.

1.3 ***"Certification of a facility"*** means the licensee's application to provide the additional services allowable under a specific license (as in Appendix "B") has received approval from the Department.

1.4 ***"Change in operator"*** means a transfer by the governing body or operator of a SAF to any other person (excluding delegations of authority to the medical or administrative staff of the SAF) of the governing body's authority to:

a) hire or fire the chief executive officer of the SAF;

b) maintain and control the books and records of the SAF;

c) dispose of assets and incur liabilities on behalf of the SAF; or

d) adopt and enforce policies regarding operation of the SAF.

The definition is not applicable to circumstances wherein the governing body of a SAF retains the immediate authority and jurisdiction over the activities enumerated in subsections (a) through (d) herein.

1.5 ***"Change in owner"*** means:

a) in the case of a SAF which is a partnership, the removal, addition or substitution of a partner which result in a new partner acquiring a controlling interest in such partnership;

b) in the case of a SAF which is an unincorporated solo proprietorship, the transfer of the title and property to another person;

c) in the case of a SAF which is a corporation:

(i) a sale, lease, exchange other disposition of all, or substantially all of the property and assets of the corporation; or

(ii) a merger of the corporation into another corporation; or
(iii) the consolidation of two or more corporations resulting in the creation of a new corporation; or

(iv) in the case of a SAF which is a business corporation, any transfer of corporate stock which results in a new person acquiring a controlling interest in such corporation; *or*

(v) in the case of a SAF which is a non-business corporation, any change in membership which results in a new person acquiring a controlling vote in such corporation.

1.6 ***"Client***" means a person who receives substance abuse services or who is judged to need substance abuse services based on the results of an initial screening. The terms "consumer" and "patient" shall be synonymous herein with the term "client."

1.7 ***"Continuing care"*** means the provision of a treatment plan process that will ensure that a client receives whatever level of care he / she needs at the time.

1.8 ***"Counseling"*** means those services provided with a primary purpose of evaluation, treatment and rehabilitation directly related to substance abuse. Such services include individual, family and group therapy provided to clients and significant others, as documented in the client's treatment plan.

1.9 ***"Courtesy dosing"*** means the provision of medication to a client by a licensed Narcotic Treatment Program that is not the client's usual or customary treatment site.

1.10 ***"Day/evening treatment"*** means treatment services which are offered as a series of individual and group sessions a minimum of four (4) days per week with a minimum of four (4) hours at a time.

1.11 ***"Department"*** refers to the Rhode Island Department of Mental Health, Retardation and Hospitals.

1.12 ***"Director"*** shall mean the Director of the Rhode Island Department of Mental Health, Retardation and Hospitals.

1.13 ***"Equity"*** means non-debt funds contributed towards the capital costs related to an initial licensure or change in owner or change in operator of a substance abuse facility which funds are free and clear of any repayment or liens against the assets of the proposed owner and/or licensee and that result in a like reduction in the portion of the capital cost that is required to be financed or mortgaged.

1.14 ***"Extended residential care"*** means any non-hospital, non-medical residential treatment program for alcohol or other drug abusing / dependent persons which provides substance abuse treatment and/or custodial care on a relatively long term basis (typically, but not necessarily, more than thirty (30) days). Such programs include, but are not limited to,

halfway houses, therapeutic communities, three-quarter houses, and transitional/long term care programs.

1.15 ***"FTE"*** means full-time equivalent.

1.16 ***"Harm reduction"*** means an approach that aims to reduce the negative consequences of drug use through utilizing a full spectrum of strategies from safer drug use to moderation management to abstinence. Oriented toward working with the whole person, harm reduction programs and policies create environments and develop strategies for change that are practical, humane and effective.

1.17 ***"HIV"*** means human immunodeficiency virus and all HIV-related viruses, as defined by the Centers for Disease Control.

1.18 ***"Initial licensure"*** means a review conducted pursuant to the provisions contained in section 4.0 herein.

1.19 ***"LAAM"*** means levo-alpha-acetyl-methadol hydrochloride (oral form), an alternative medication used in narcotic treatment, as an additional pharmacotherapy for opiate addiction.

1.20 ***"Licensee"*** means the individual agency or other legal entity responsible to the Department for the operation of a SAF that is licensed by the Department.(~~,~~)

1.21 ***"Licensing agency"*** shall mean the Rhode Island Department of Mental Health, Retardation and Hospitals.

1.22 ***"Long term care"*** means a community residence which on a 24-hour supervised basis, provides basic shelter, food, substance abuse education and treatment/rehabilitation activities, financial information and emotional support to persons with chronic chemical dependency who are not appropriate for, or who have exhausted, the more traditional residential and outpatient substance abuse treatment options. The length of stay is flexible and based on client need and individual treatment plans.

1.23 ***"Long term opiate detoxification"*** treatment is for a period of more than thirty (30) days, but not in excess of one hundred eighty (180) days within a Narcotic Treatment Program.

1.24 ***"Medical detoxification"*** services are provided in a hospital or suitably equipped medical setting.

1.25 ***"Medically supervised withdrawal"*** means a gradual withdrawal, within a Narcotic Treatment Maintenance Program, of the treatment agent using decreasing doses in such a manner that a zero dose of the treatment agent is achieved over a period of time, as determined by the physician in conjunction with the client.

1.26 ***"Methadone"*** means methadone hydrochloride (oral form), a synthetic narcotic that has been demonstrated to be an effective agent in the treatment (maintenance or

withdrawal/detoxification) of opiate dependence. Its purpose is to eliminate the withdrawal symptoms and reduce the craving associated with regular or long term opiate use.

1.27 ***"Minor/child"*** means any person under eighteen years of age.

1.28 **"*Opioid treatment facility"*** means an organization that administers or dispenses a narcotic drug to a narcotic addict for maintenance or detoxification treatment, provides, when appropriate or necessary, a comprehensive range of medical and rehabilitative services, is approved by the State authority and the Food and Drug Administration and that is registered with the Drug Enforcement Administration to use a narcotic drug for the treatment of narcotic addiction.

1.29 ***"Outpatient detoxification"*** means the medical management, as provided through outpatient services, of the physiological and psychological withdrawal symptoms to insure that medical or psychological complications do not develop as a result of abstinence from alcohol or certain other drugs.

1.30 ***"Outpatient facility***" means a program/facility which makes available substance abuse treatment services a minimum of five (5) days per week, is staffed and otherwise equipped to deliver: assessment, evaluation, individual, group and/or family counseling services, as well as referral, follow-up, aftercare and, in some cases, medication; and ensures continuity of care **(see also section 23.0 herein).**

1.31 ***"Outpatient services"*** means individual, family, or group counseling services provided for clients who do not require residential service, or day/evening treatment, for less than 9 contact hours per week. Clients remain in the community but receive services such as counseling, assessment and evaluation, case management, referral services, follow-up or continuing care and, in some cases, medication.

1.32. ***"Parenteral"*** means the introduction of a substance into a human being other than through the gastrointestinal tract or lungs; refers particularly to intravenous, subcutaneous, intramuscular or intramedullary injections.

1.33 ***"Patient Support Staff"*** member of the counseling staff that assists and guides high-risk substance abuse patients with coordination of collateral services as identified in the assessment and treatment plan.

1.34 ***"Person"*** means any individual, governmental unit, corporation, company, association, or joint stock association and the legal successor thereof.

1.35 ***"Physical examination"*** shall mean an examination by a duly licensed physician, nurse practitioner or physician assistant. that shall include physical evaluation for possible cardiopulmonary, hepatic, neurological or infectious problems. It should also include a tuberculin skin test unless there is documented evidence of such a skin test within the previous six (6) months.

As part of the physical examination, the attending physician (or other authorized health care provider) shall order laboratory work, as necessary, to treat a client in a specific level of care.

1.36 ***"Physician"*** means any individual licensed to practice medicine or osteopathy in this state under the provisions of R.I.Gen. Laws 5-37-1 *et seq.*

1.36.1 ***"Attending physician"*** refers to a physician (who may or may not be on the SAF staff) identified by the client/family as having a significant role in the determination and delivery of the individual's medical care.

1.36.2 ***"Physician Extender"*** a Physician Assistant or Nurse Practitioner that is licensed to practice by the State of Rhode Island.

1.37 ***"Premises***" means a tract of land and the buildings thereon where direct client care services are provided.

1.38 ***"Professional certification"*** means fulfilling the requirements of a professional authority, such as a national accrediting body, approved by the Director and completed as a necessary prerequisite to licensure.

1.39 ***"Recovery"*** means a process of overcoming both physical and psychological dependence on a drug (including alcohol) and / or drugs of abuse, with a commitment to sobriety. *Recovery* refers to the overall goal of helping a client to achieve overall health and well-being.

1.40 A ***"reportable incident***" means any happening that is not consistent with the routine operation of the program or care of the client. It may be an accident or a situation that a reasonable person might expect to result in an accident. This may involve a client, visitor, staff or any other person on the premises.

1.41 ***"Residential rehabilitation***" means a short term residential treatment program which offers intensive substance abuse treatment services and medical and psychological support in a non-hospital, residential setting. Residential rehabilitation may or may not include detoxification services for substance abusers.

1.42 ***"Satellite"*** means adjunct drug-free substance abuse treatment services provided off-site from the parent facility/program under which it is licensed, for a maximum of twenty (20) hours per week, to a minimum of five (5) clients, on average, and is in compliance with all applicable requirements as stated herein.

1.43 ***"Short term detoxification"*** is for a period not to exceed thirty (30) days.

1.44 ***"Social setting detoxification"*** means a residential treatment program for persons who require alcohol and/or drug detoxification services of a non-medical nature.

1.45 ***"State Methadone authority"*** means the agency designated by the Governor or other appropriate official to exercise the responsibility and authority within the State or Territory

for governing the treatment of narcotic addiction with a narcotic drug, this shall be the Department of Mental Health, Retardation and Hospitals, Division of Substance Abuse.

1.46 ***"Substance abuse facility,"*** hereinafter referred to as SAF/program, shall mean a structurally distinct public or private health care establishment, institution or facility, primarily constituted, staffed and equipped to deliver substance abuse treatment and/or rehabilitative services to the general public and known by such terms as: general residential facility, outpatient clinic, chemical dependency program, community residence, day/evening treatment program, narcotic treatment program, extended residential care, social setting detoxification facility , medical detoxification facility, halfway house, three-quarter house, transitional care facility, therapeutic community, or long term care which is not a part of a hospital; providing however, that the term "substance abuse facility and program" shall not apply to organized ambulatory care facilities owned and operated by professional service corporations as defined in R.I.Gen. Laws 7-5.1-1 *et seq*. (the "Professional Service Corporation Law"), or to a private practitioner's (physician, dentist or other health care provider) office, or group of practitioners' offices (whether owned and/or operated by an individual practitioner, alone or as a member of a partnership, professional service corporation, organization or association).

1.47 ***"Transitional care"*** means a low intensity treatment service that primarily provides clients with time to explore and consider more intensive treatment options, with support and guidance from staff. The typical length of stay is from seven (7) to thirty (30) days, at which time the client may be referred to community-based treatment services or to long term care.

1.48 ***"Treatment program"*** means a planned, structured service delivery system, structured to provide specific components that address the needs of its clients.

Section 2.0 ***General Requirements for Licensure***

2.1 No person acting severally or jointly with any other person shall establish, conduct or maintain a SAF in this state without a license in accordance with the requirements of the rules and regulations herein.

2.2 A certificate of need (CON) is required as a precondition to the establishment of a new residential SAF, and such other activities in accordance with R.I. Gen. Laws 23-15-2(10).

2.3 No SAF providing substance abuse treatment services as defined herein shall represent itself as a substance abuse facility and/or program unless licensed as a substance abuse facility and/or program pursuant to the provisions herein.

2.4 Each premise of a licensed SAF shall comply with all pertinent provisions herein consistent with the scope of services provided at such premise.

2.5 Any SAF which operates as an affiliate, or as a satellite, of a parent organization shall have a written agreement on file which stipulates the nature of the relationship. This document should be on file at both the parent and satellite facilities.

2.6 A SAF parent organization may apply for a license in any of the following categories (see licensing schematic in Appendix "B"):

1. residential facility;
2. outpatient facility;
3. narcotic treatment.

Only one (1) license shall be required for each premise. Satellites shall not require a separate license, as the parent organization's license shall include any satellites and the address(es) of said satellite(s) shall appear on the parent organization's license.

2.6.1 Any SAF licensed as a residential facility is eligible to apply for certification in one (1) or more of the following areas:

1. detoxification;
2. residential rehabilitation;
3. extended residential.

2.6.2 Any SAF licensed as an outpatient facility shall be certified as an outpatient drug free facility. Services allowed under this level of care include day treatment and outpatient services. Outpatient detoxification services shall require an additional certification to provide these services.

2.6.3 Any SAF providing narcotic treatment services shall have a narcotic treatment license from the Department and be registered with the Drug Enforcement Administration (DEA) and the Food and Drug Administration (FDA), as applicable.

2.7 As indicated in Appendix "B", each SAF licensed and certified to provide a specific level of care may provide any of the allowable services encompassed by that level of care without obtaining any additional license(s), except as stated in section 2.6.2 (above).

2.7.1 Any services provided under a specific certification level (e.g., detoxification) shall be provided in accordance with the requirements of Part V herein.

2.7.2 Satellite facilities shall provide outpatient drug free services only.

2.8 In accordance with the provisions of R.I. Gen. Laws 21-28-3.21 (entitled "Operation of Treatment and Rehabilitations Programs for Drug Dependent Persons"), approval (i.e., a controlled substance registration) for the operation of a treatment and rehabilitation program for drug dependent persons shall be obtained prior to the initiation of the program by submission of an application to the Department of Mental Health, Retardation and Hospitals and appropriate federal authorities.

Section 3.0 ***Application for License and for Initial Licensure or Changes in Owner, Operator, or Lessee***

3.1 Application for a license to conduct, maintain or operate a SAF and any satellites shall be made to the licensing agency upon forms provided by it, and shall contain such information as the licensing agency reasonably requires, including but not limited to, evidence of ability to comply with the rules and regulations herein.

3.2 A notarized listing of names and addresses of direct and indirect owners whether individual, partnership, or corporation, with percentages of ownership designated, shall be provided with the application and / or renewal application for licensure. The list shall include each owner (in whole or in part) of the SAF. The list shall also include all officers, directors and other persons or any subsidiary corporation owning stock, if the SAF is organized as a corporation, and all partners if the SAF is organized as a partnership.

Section 4.0 ***Issuance and Renewal of License and Initial Licensure Review***

4.1 Upon receipt of an application for a license, the licensing agency shall issue a license or renewal thereof for a period of no more than two (2) years if the applicant meets the requirements of the rules and regulations herein. Said license, unless sooner suspended or revoked, shall expire no more than two years from the date of issuance and may be renewed bi-annually after inspection and approval by the licensing agency.

4.2 A license shall be issued to a specific parent organization for a specific location or locations and shall not be transferable, except with the written approval of the licensing agency. The license shall be issued only for the individual owner, operator, or lessee or to the corporate entity responsible for its governance.

4.3. The decision of the licensing agency will be rendered within ninety (90) days from acceptance of the application.

4.4 All applications reviewed by the licensing agency and all written materials pertinent to licensing agency review shall be accessible to the public upon request.

4.5 In conducting reviews of such applications the Licensing Agency shall specifically consider and it shall be the applicant's burden of proof to demonstrate:

4.5.1 The character, commitment, competence, and standing in the community of the proposed owners, operators or directors of the SAF as evidenced by:

(A) In cases where the proposed owners, operators, or directors of the SAF currently own, operate, or direct a SAF, or in the past five years owned, operated or directed a SAF, whether within or outside Rhode Island, the demonstrated commitment and record of that (those) person(s):

(i) in providing safe and adequate treatment to the individuals receiving the SAF's services ;

(ii) in encouraging, promoting and effecting quality improvement in all aspects of SAF services; and

(iii) in providing appropriate access to SAF services;

(B) A complete disclosure of all individuals and entities comprising the applicant and

(C) The applicant's proposed and demonstrated financial commitment to the SAF;

4.5.2 The extent to which the SAF will provide or will continue without material effect on its viability at the time of change of owner, operator, or lessee, to provide safe and adequate treatment for individuals receiving the SAF's services as evidenced by:

(A) The immediate and long term financial feasibility of the proposed financing plan;

(i) The proposed amount and sources of owner's equity to be provided by the applicant;

(ii) The proposed financial plan for operating and capital expenses and income for the period immediately prior to, during and after the implementation of the change in owner, operator or lessee of the SAF;

(iii) The relative availability of funds for capital and operating needs;

(iv) The applicant's demonstrated financial capability;

(v) Such other financial indicators as may be requested by the Licensing Agency;

4.5.3 The extent to which the SAF will provide or will continue to provide safe and adequate treatment for individuals receiving the SAF's services and the extent to which the facility will encourage quality improvement in all aspects of the operation of the SAF as evidenced by:

(A) The applicant's demonstrated record in providing safe and adequate treatment to individuals receiving services at facilities owned, operated, or directed by the applicant; and

(B) The credibility and demonstrated or potential effectiveness of the applicant's proposed quality assurance programs;

4.5.4 The extent to which the facility will continue to provide access to treatment with respect to traditionally underserved populations as evidenced by:

(A) In cases where the proposed owners, operators, or directors of the SAF currently own, operate, or direct a SAF, or in the past five years owned, operated or directed a SAF, both within and outside of Rhode Island, the demonstrated record of that person(s) with respect to access of traditionally under served populations to its facilities;

(B) The proposed immediate and long term plans of the applicant to ensure adequate and appropriate access to the programs and health care services to be provided by the SAF;

4.5.5 In consideration of the proposed continuation or termination of services by the SAF:

(A) The effect(s) of such continuation or termination on the provision of access to safe and adequate treatment of individuals, including but not limited to traditionally underserved populations;

4.5.6 And, in cases where the application involves a merger, consolidation or otherwise legal affiliation of two or more facilities, the proposed immediate and long term plans of such facilities with respect to the programs to be offered and services to be provided by such facilities as a result of the merger, consolidation or otherwise legal affiliation.

4.6 Subsequent to reviews conducted pursuant to these regulations, the issuance of a license by the licensing agency may be made subject to any condition, provided that no condition may be made unless it directly relates to the statutory purpose expressed in R. I. Gen. Laws 40.1-1-13. This shall not limit the authority of the licensing agency to require correction of conditions or defects which existed prior to the proposed change in owner, operator, or lessee and of which notice had been given to the SAF by the licensing agency.

4.7 A license issued hereunder shall be the property of the Department and loaned to such licensee, and it shall be kept posted in a conspicuous place on the licensed premises. A license shall immediately become void and shall be returned to the licensing agency when operation of the SAF is discontinued, or when, without notice to and approval of the Department, any changes in ownership occur in accordance with these rules and regulations.

Section 5.0 ***Inspections***

5.1 The licensing agency shall make or cause to be made such inspections and investigations as it deems necessary, including treatment records, in accordance with the rules and

regulations herein. Staff from the licensing agency shall have: 1. the right of entrance, as necessary and appropriate; 2. the privilege to inspect all premises; and 3. access to all records for the purpose of ascertaining the compliance with regulations relative to the quality of services being rendered. Said staff may interview clients or any other interested parties for the purpose of completing this inspection.

5.1.1 Refusal to permit inspections shall constitute a valid ground for license denial, suspension or revocation.

5.2 Every SAF shall be given prompt notice by the licensing agency of all significant deficiencies reported as a result of an inspection or investigation.

5.3 If there is reasonable evidence that the SAF or its satellite is not in operation, the license may be revoked after due notice and opportunity for hearing.

Section 6.0 ***Deficiencies and Plans of Correction***

6.1 The licensing agency shall notify the governing body or other SAF legal authority of violations of individual standards through a notice of deficiencies which shall be forwarded to the SAF unless the Director determines that immediate action is necessary to protect the health, welfare, or safety of the public (or any member thereof) through the issuance of an immediate compliance order.

6.2 A SAF which received a notice of deficiencies must submit a plan of correction, to include time frames for completion, to the licensing agency within fifteen (15) days of the date of the notice of deficiencies. The plan of correction shall detail any requests for variances as well as document the reasons therefore.

6.3 The licensing agency will be required to approve or reject the plan of correction submitted by a SAF in accordance with section 6.2.

6.4 If the licensing agency rejects the plan of correction, or if the SAF does not provide a plan of correction within the fifteen (15) day period stipulated in section 6.2 above, or if a SAF whose plan of correction has been approved by the licensing agency fails to execute its plan within a reasonable time, the licensing agency may invoke the sanctions enumerated in section 7.0 herein. If the SAF is aggrieved by the action of the licensing agency, the facility may appeal the decision and request a hearing in accordance with R.I. Gen. Laws 42-35-1 *et seq.* (Administrative Procedures Act).

6.5 The notice of the hearing to be given by the Department shall comply in all respects with the provisions of R.I. Gen. Laws 42-35-1 *et seq.*. The hearing shall in all respects comply with the provisions therein.

Section 7.0 ***Denial, Suspension, Revocation of License or Curtailment of Activities***

7.1 The licensing agency is authorized to deny, suspend or revoke the license of (or to curtail the activities of) any SAF which: (1) has failed to comply with the rules and regulations

pertaining to the licensing of SAF; and (2) upon inspection when there is no reasonable and substantial evidence that the program is in operation and due notice and opportunity for hearing has been given .

7.1.1 Reports of deficiencies noted in inspections conducted in accordance with section 5.0 herein shall be maintained on file in the licensing agency, and shall be considered by the licensing agency in rendering determinations to deny, suspend or revoke the license or to curtail activities of a SAF.

7.2 Whenever a final action shall be proposed to deny, suspend or revoke the license of (or to curtail the activities of) a SAF, the licensing agency shall notify the SAF by certified mail, setting forth reasons for the proposed action, and the applicant or licensee shall be given an opportunity for a prompt and fair hearing in accordance with R.I. Gen. Laws 42-35-9 and pursuant to the provision of section 29.0 herein.

7.2.1 However, if the licensing agency finds that public health, safety or welfare imperatively requires emergency action and incorporates a finding to that effect in its order, the licensing agency may order summary suspension of license or curtailment of activities pending proceedings for revocation or other action in accordance with R.I. Gen. Laws 42-35-14(c).

7.3 The appropriate state and federal agencies shall be notified of any action taken by the licensing agency pertaining to either denial, suspension, or revocation of license or curtailment of activities.

7.4 Thirty (30) days prior to the voluntary cessation of operation of any SAF, the Department shall be notified and provided with a plan for orderly closure and transfer of clients and records.

PART II *ORGANIZATION & MANAGEMENT*

Section 8.0 *Governing Body & Management*

8.1 Each SAF shall have an organized governing body or equivalent legal authority, ultimately responsible for: (1) the program and fiscal management and operation of the SAF; (2) the assurance of the quality of care and services; and (3) the compliance with all federal, state and local laws and regulations pertaining to SAFs and the rules and regulations herein.

8.2 The governing body, or equivalent legal authority, shall provide appropriate personnel, physical resources, and equipment to facilitate the delivery of substance abuse treatment services, during established hours of operation.

8.3 The governing body, or equivalent legal authority, shall designate an administrator who shall be operationally responsible for the management and operation of the SAF.

8.4 The governing body, or equivalent legal authority, shall adopt by-laws, or acceptable equivalent, defining the responsibilities for the operation and performance of the SAF and

identifying purposes and means of fulfilling such. In addition, the governing body or equivalent legal authority shall establish administrative policies pertaining to no less than the following:

8.4.1 the qualifications and responsibilities of the administrator and the medical director;

8.4.2 the modalities of substance abuse treatment services to be provided;

8.4.3 linkages or referrals among other health care providers to ensure continuity of care. These shall include a mechanism for recording, transmitting and receiving information essential to the continuity of client/family care;

8.4.4 quality assurance plan for client care and services;

8.4.5 management's responsibilities for contracted services;

8.4.6 such other matters as may be relevant to the organization and operation of the SAF.

8.5 The governing body shall be responsible to establish a mechanism through the organization's by-laws or policies and procedures to assure that duly qualified physicians and other professionals are assigned to agency services based on appropriate education, training, experience and evidence of current professional practice and licensure as may be required by law.

Section 9.0 ***Administrator***

9.1 The governing body or equivalent legal authority shall appoint an administrator(s) who shall be operationally responsible for: (1) the management and operation of the SAF; (2) the compliance with policies, rules and regulations and statutory provisions pertaining to the health and safety of clients; (3) serving as liaison between the governing body or equivalent legal authority and the staff; and (4) the planning, organizing and directing of such other activities as may be delegated by the governing body.

Section 10.0 ***Quality Improvement / Management System***

10.1 The SAF shall maintain a written annual quality improvement / management plan which will include but not be limited to the following: statements of annual goals, objectives (steps) to accomplish goals; statement of person(s) responsible for the implementation / monitoring of the plan; statement describing the scope of services that will utilize the plan; and a statement listing the important aspects of care (high volume, high risk, sentinel events and client satisfaction).

10.1.1 The quality improvement plan will include indicators that are quantifiable (i.e., measurable).

a) The SAF shall develop reasonable percentage benchmarks for the indicators.

b) The SAF shall describe the methodology(ies) utilized to monitor the indicators.

c) The SAF shall list the data source(s) which contribute to the attained percentage achieved in each indicator.

10.1.2 This quality improvement plan shall provide for an annual review of the effectiveness of the SAF's services.

10.1.3 The annual quality improvement report shall be documented together with all revisions made to goals, objectives, policies and procedures.

10.1.4 The resulting revisions of goals, objectives, policies and procedures shall be made available to all SAF personnel.

Satellite Facilities

10.2 Each satellite shall complete an annual review (e.g., quality improvement plan) of the effectiveness of the services provided on-site and document the results of said review along with any revisions made to goals, objectives, policies or procedures, as applicable.

Section 11.0 ***Personnel***

11.1 The SAF shall have a policy and procedure manual which is reviewed and updated annually, and shall include at least but not be limited to:

11.1.1 ***Personnel policies***

Such policies shall include at least but not be limited to the following:

a) an affirmative action policy statement;

b) procedures for hiring, firing and promotion;

c) written functional job descriptions as described in 11.7.3;

d) Each SAF shall be responsible for maintaining a policy of non-discrimination in the provision of services to clients and shall employ persons without regard to race, color, creed, national origin, gender, religion, sexual orientation, age handicapping condition or degree of handicap, in accordance with Title VI of the Civil Rights Act of 1964; U.S. Executive Order #11246 entitled "Equal Employment Opportunity"; U.S. Department of Labor regulations; Title V of the Rehabilitation Act of 1973, as amended; the Rhode Island Fair Employment Practices Act; R. I. Gen. Laws 28-5-1

et seq.; the Americans with Disabilities Act; and any other federal or state law relating to discriminatory practices.

e) Annually, the SAF shall evaluate the job performance of each staff member;

f) a procedure for written staff evaluations;

g) a procedure for informing personnel of their rights and benefits, including disciplinary procedures;

h) a policy and procedure related to orientation of new staff, including information and training relating to state and federal laws governing confidentiality of client information;

i) The SAF shall have a written policy related to Ethical Standards / Codes of Conduct which includes staff / client fraternization. This policy shall be consistent with the Ethical Standards of the RIBCCDP. All staff employed by the SAF shall sign a copy of the Ethical Standards / Codes of Conduct to indicate their knowledge of responsibility to abide by these standards.

j) a written schedule of in-service training and development for staff, maintained and updated annually;

k) a written policy for a drug free work place that is consistent with all federal, state and Departmental regulations.

11.2 The SAF shall have employed either directly or on a consultant basis, the services of one (1) or more appropriately trained professional(s) who shall provide clinical supervision as required by these regulations.

11.2.1 An appropriately trained clinical supervisor shall be defined as:

a) an individual having a minimum of a master's degree in a clinically related field, with a minimum of two (2) years of clinical practice experience and hold a Rhode Island independent license in a clinical specialty (e.g. psychology, mental health counseling, marriage / family and child counseling, clinical social work, medicine, registered nursing) with a certification in chemical dependency from a nationally recognized entity whose certification criteria include clinical experience, clinical supervision, and an examination which are substantially similar to the requirements of the RI Board for Licensing of Chemical Dependency Professionals. The Department reserves the right to disqualify such certification for cause. Must have experience as a clinical supervisor or at least have taken a Department approved course in clinical supervision. ;

or

b) a Licensed Chemical Dependency Professional; and, at a minimum, have taken a Department approved course in clinical supervision;

or

c) an individual who is licensed as a Chemical Dependency Clinical Supervisor by the Rhode Island Board for Licensing of Chemical Dependency Professionals.

11.2.2 All independent contractors, who do not meet the requirements of 11.2.1 herein, must obtain clinical supervision which must be provided and documented by a supervisor who qualifies under 11.2.1 herein.

11.3 The SAF shall be staffed with appropriate professional and ancillary personnel who shall be assigned duties and responsibilities which are consistent with their training and experience, and services rendered.

11.3.1 No less than fifty percent (50%) of staff providing direct therapeutic services shall hold a Rhode Island license in a clinical specialty (e.g., psychology, mental health counseling, marriage/family and child counseling, clinical social work, medicine, registered nursing) with a certification in chemical dependency from a nationally recognized entity whose certification criteria include clinical experience, clinical supervision, and an examination, which are substantially similar to the requirements of the RI Board for Licensing of Chemical Dependency Professionals. The Department reserves the right to disqualify such certification for cause.

or

shall be licensed chemical dependency professionals.

11.3.2 The remaining fifty percent (50%) shall be actively engaged in the process of meeting the requirements of section 11.3.1 (above) and supervised, as appropriate.

11.3.3 Each SAF shall develop and maintain a written professional development plan that shall detail the SAF's progress in meeting the requirements of this section. Said plan shall include, at a minimum, the existing professional staffing plan; the resources identified as necessary for achieving the professional staffing plan required herein; and the time line for meeting said requirements.

Minor Clients

11.4.1 Residential programs that treat minor clients shall provide staffing that allows for constant adult supervision at all times and includes the following:

a) awake staff coverage twenty-four (24) hours per day;

b) direct care staff to client ratio is at least 1:10, when clients are awake and 1:20 when clients are asleep.

Residential Facilities

11.4.2 In residential settings, SAF staff responsible for resident care shall be available on site twenty four (24) hours per day.

11.5 The SAF shall provide for and document a minimum of one (1) hour of clinical supervision per FTE per week (or four (4) hours per month) for each counselor providing treatment services.

11.5.1 Licensed counselors shall have a minimum of one (1) hour of individual supervision each month. Each month, the three (3) remaining hours of mandatory supervision may be in a group setting.

11.5.2 All other counselors who do not hold a license shall have a minimum of two (2) hours of individual supervision each month. Each month, the two (2) remaining hours of mandatory supervision may be in a group setting.

11.6 The SAF shall address the mental health needs of their clients by QSOA, direct client referral, consultation or direct employment.

11.7 The SAF shall maintain confidential personnel records for each staff member, including volunteers and/or fee for service staff. These records shall be reviewed and updated annually and shall include, but not be limited to, all of the following:

11.7.1 Completed job application, and/or resume;

11.7.2 Statements of references, either by letters or by documentation of conversations;

11.7.3 Written functional job descriptions: These descriptions shall be reviewed and updated annually, and shall include minimal qualifications for the position, major duties, responsibilities, reporting supervisors, and positions supervised, and must be signed and dated by the individual employed.

a) Agencies employing independent contractors must have a copy of the contract stipulating the above information.

11.7.4 Evidence of credentials, professional licensure, and/or certification, including renewals as applicable;

11.7.5 Documentation of education and or training subsequent to employment, including course work related to counselor certification;

11.7.6 Documentation of attendance at in-service training staff meetings and clinical supervision for counseling staff;

11.7.7 Documentation of at least one performance evaluation annually;

11.7.8 A copy of each employee's signed statement indicating awareness of all applicable state and federal rules and regulations regarding confidentiality;

11.7.9 A signed copy of the SAF's Code of Ethics (clinical staff).

11.7.10 A signed copy of the SAF's Code of Conduct (all non-clinical staff).

11.8 *Personnel Criminal Records Check*

11.8.1 The SAF shall request a copy of all prospective employee's current Bureau of Criminal Identification Record (in the case of NTP's they will also abide by the requirements of federal law 21 CFR 1301.76). Said employee, through the employer, shall apply to the bureau of criminal identification of the state or local police department for a criminal records check. Fingerprinting shall not be required as part of this check

11.8.2 In such circumstances where prior criminal convictions are indicated, the prospective employee may be employed subject to written approval of the governing body of the SAF. This requirement shall apply to all agency positions.

11.8.3 In those situations in which no disqualifying information (as defined below) has been found, the bureau of criminal identification (BCI) of the state or local police shall inform the prospective employee and the employer in writing.

a) ***Disqualifying information,*** means information produced by a criminal records review pertaining to any conviction~~,~~ for the following crimes will result in a letter to the employee and employer disqualifying the applicant from said employment: murder, voluntary manslaughter, involuntary manslaughter, any degree of sexual assault, assault on persons sixty (60) years of age or older, assault with intent to commit specified felonies (murder, robbery, rape, burglary, felony assault, client abuse, neglect or mistreatment of clients, burglary, first degree arson, robbery, felony drug offenses,. An employee against whom disqualifying information has been found may request that a copy of the criminal background report be sent to the employer who shall make a judgment regarding the employment and / or continued employment of the individual.

b) For purposes of this section, the term "conviction" shall mean, in addition to judgments of conviction entered by a court subsequent to a finding of guilty or a plea of guilty, those instances where the defendant has entered a plea of nolo contendere and has received a sentence of probation and those instances where a defendant has entered into a deferred sentence agreement with the Attorney General.

11.8.4 Any disqualifying information, (as defined above), shall be conveyed to the prospective employee, in writing, by the bureau of criminal identification. The employer shall also be notified that disqualifying information has been discovered, but shall not be informed of the nature of the disqualifying information. An employee against whom disqualifying information has been found may request that a copy of the criminal background report be sent to the employer who shall make a judgement regarding the continued employment of the employee.

11.8.5 The employer shall maintain on file, subject to inspection by the Department, evidence that criminal records checks have been initiated on all employees seeking employment, as well as the results of said check.

11.8.6 If the prospective employee has undergone a criminal records check within eighteen (18) months of an application for employment, then an employer may request from the bureau a letter indicating if any disqualifying information was discovered. The bureau shall respond without disclosing the nature of the disqualifying information.

Section 12.0 ***Rights of Clients***

12.1 Each SAF shall develop and maintain a comprehensive written statement of individual client rights. This statement shall include the following rights:

12.1.1 To have treatment services provided without bias, based on race, religion, sex, sexual orientation, ethnicity, age, handicap or handicapping condition;

12.1.2 To be informed in the language that the client understands;

12.1.3 To be informed about what to expect during the treatment process;

12.1.4 To be informed of the cost of services rendered to the client and to his/her family as soon as the information is available;

12.1.5 To receive a copy of the client handbook / notifications which contains guidelines for treatment including program rules, services provided, clients rights and other pertinent information;

12.1.6 To participate in the planning of his/her individualized treatment plan and a periodic review of it;

12.1.7 To request a review of his/her treatment plan at any time during treatment, and/or to obtain the opinion of a qualified outside consultant regarding his/her treatment plan at the client's own expense if he/she so desires;

12.1.8 To take an active part in planning aftercare activities and referrals to other services he/she may need;

12.1.9 Health care requires informed consent, indication that the client has been made aware of the proposed modalities of treatment, medications involved in treatment, the risks and benefits of such treatment, appropriate alternative treatment modalities and the risks of treatment versus no treatment.

12.1.10 To refuse treatment or any procedures or specific medication and be advised of the impact (if any) on his / her treatment to include any procedures which are unusual, hazardous and/or experimental;

12.1.11 To have competent, qualified, experienced clinical staff to supervise and carry out his/her treatment;

12.1.12 To be referred to an alternate treatment setting if he/she is inappropriate or ineligible for treatment at the present level of care;

12.1.13 To expect confidentiality from the entire staff with respect to his/her identity, and all aspects of care;

12.1.14 To be encouraged and assisted throughout his/her treatment to understand and exercise his/her rights as a client without fear of restraint, interference, discrimination or reprisal.

12.1.15 The statement (cited in section 12.1) must also include client rights with respect to performing services for the SAF.

1. No client shall be requested to perform services for the SAF which are not stated as part of his/her program treatment plan.

2. No client shall be allowed to perform services in lieu of treatment fees.

12.1.16 To know the recommended level of care for his / her treatment and as indicated by the clients presenting problems and alternate treatment options.

12.1.17 Before being asked to consent to participate in a research project, to be informed of the following:

a) the benefits to be expected;

b) the potential discomforts and risks;
c) alternative services that might benefit them;
d) the procedures to be followed, especially those that are experimental in nature; and
e) their right to refuse to participate in any research project without compromising their access to the agencies services.

12.2 Each SAF shall have a formal grievance procedure in place for allowing the client (and/or legal guardian) to present suggestions or grievances. All clients shall be given written notice of these procedures upon entry into the SAF and upon request and documentation of this shall be in the client record.

12.3 Each SAF shall display in a conspicuous place in the licensed SAF a copy of the "Rights of Clients" provided for in these regulations. A copy of this document shall be signed by the client and placed in the client's treatment record.

Residential Facilities

12.4 In a residential facility, each SAF resident shall have the right to private written and verbal communication, including access to a public telephone and uncensored mail, consistent with the therapeutic process. Any reason(s) for curtailing these rights shall be explained to the client and documented in the treatment record.

12.5 In a residential facility, each SAF resident shall have visiting privileges with significant others in a time, place and manner consistent with the therapeutic process.

12.5.1 When visiting privileges are denied, this must be explained to the client and written documentation of same must be entered into the treatment record, giving circumstances and justification. Such denials shall be periodically reviewed by medical and administrative officials.

12.6 The prospective resident, when appropriate, shall have the opportunity to visit the SAF residential facility prior to admission, and shall participate in making the decision regarding his admission, except when admission occurs under the provisions of R.I. Gen. Laws 23-1.10-11 ("Emergency Commitment") and R.I. Gen. Laws 23-1.10-12 ("Involuntary Commitment-Alcoholics") This shall be documented in the intake notes.

Section 13.0 ***Administrative Records***

13.1 Each SAF shall maintain such administrative records as may be deemed necessary by the licensing agency. These records shall include but not be limited to:

13.1.1 monthly statistical summary of numbers of visits and number of clients seen;

13.1.2 a copy of the long and short range strategic plans of the agency; and

13.1.3 an administrative record, log book or appointment book containing pertinent data such as client's name, record number, age, sex, date and stated reason for the appointment and time of visit and the name of the provider of service.

Residential Facilities

13.2 Each SAF licensed as a residential facility shall maintain a written cooperative agreement with a hospital to care for any residents in need of emergency care.

13.3 Each SAF licensed as a residential facility shall maintain a written cooperative agreement with a detoxification facility, as needed.

Section 14.0 ***Uniform Reporting System***

14.1 Each SAF shall establish and maintain records and data in such a manner as to make uniform the system of periodic reporting. The manner in which the requirements of the regulation may be met shall be prescribed from time to time in directives promulgated by the Director.

14.2 Each SAF shall make available for review upon request of the licensing agency detailed statistical data pertaining to its operation, services provided, including numbers of clients, range of problems presented and treated~~.~~. Such reports and data shall be made at such intervals and by such dates as determined by the Director.

14.3 The licensing agency is authorized to make the reported data available to any state or federal agency concerned with or exercising jurisdiction over the SAF.

14.4 The directives promulgated by the Director pursuant to these regulations shall be sent to each SAF to which they apply. Such directives shall prescribe the form and manner in which the statistical data required shall be furnished to the licensing agency.

PART III ***HEALTH CARE SERVICES***

Section 15.0 ***Management of Services***

15.1 Each SAF shall be organized to provide services with adequate professional and ancillary staff to ensure that all persons are treated and discharged in accordance with generally accepted standards of professional practice. Further, the SAF shall ensure that all services, including arranged services, are rendered in a safe and effective manner consistent with acceptable standards of practice and the requirements herein.

15.1.1 Each parent SAF that operates a satellite under its SAF license shall be responsible for: (1) the program operations and fiscal management of the satellite; (2) the assurance of quality of care and continuity of services; and (3) the compliance with all federal, state and local laws and regulations pertaining to SAFs and the rules and regulations herein.

15.1.2 Each satellite shall maintain on-site a copy of the SAF's policies and procedures pertaining to the provision of all services, including, but not limited to, the requirements of this section.

15.2 The SAF must maintain written program policies which shall include but not be limited to the following:

15.2.1 There shall be a written description of all programs and services available to clients, which shall be designed to promote the client's efforts toward recovery. This shall include at least a listing of hours and days of operation, any available emergency services, a description of any cooperative agreement with other agencies, and description of mechanisms for providing services not directly provided by the SAF.

15.2.2 Policies and procedures relating to functions and organization, which shall be reviewed for consistency with applicable Department regulations.

15.2.3 A written statement of SAF's goals for client's progression into least restrictive program activity or treatment situation.

15.3 All programs shall directly provide the following services:

a) Individual, group, and/or family counseling activities.

b) Information/education related to drug, alcohol and/or substance abuse including HIV/AIDS, TB, Hep A, B, C , STD's, harm reduction and other associated medical conditions.

c) Education related to substance-abuse-related support services such as: AA, NA, CA, Al-Anon, Al-Ateen.

15.4 Each SAF shall develop and maintain a statement of admission criteria which shall include at least the following information regarding the client population:

15.4.1 Nature and extent of the disabling condition(s) served

15.4.2 Chronological age ranges served

15.4.3 Any specific restrictions related to:

a) geographic residence
b) legal status
c) other

15.5 The statement of admission criteria shall include a guarantee that no otherwise qualified applicant shall be denied admission to the program solely on the basis of age, race, creed,

color, religion, sex, sexual orientation, national origin, handicapping condition or degree of handicap.

Further, Each SAF shall be responsible for maintaining a policy of non-discrimination in the provision of services to clients in accordance with Title VI of the Civil Rights Act of 1964; Title V of the Rehabilitation Act of 1973, as amended; R. I. Gen. Laws 28-5-1 *et seq*.; the Americans with Disabilities Act; and any other federal or state law relating to discriminatory practices.

15.6 The SAF shall develop and maintain an admission procedure that shall include at least the following:

15.6.1 Pre-admission requirements

15.6.2 Time, days of intakes

15.6.3 The procedures to be followed, including those for referral, when an applicant is found to be ineligible for admission.

15.6.4 Prior to admission, the client and/or legal guardian shall be informed of any charges for services.

15.7 The SAF shall maintain and enforce a written description of policies and procedures for its staff to follow in treatment planning and documentation of services.

15.8 The SAF shall maintain and enforce a written description of policies and procedures for its staff to follow in assuring continuity of service.

15.9 The SAF shall maintain a written policy that the SAF shall assume responsibility for knowing where and how services indicated in the treatment plan may be obtained and shall assist the client in obtaining such services.

15.10 The SAF shall maintain a written policy that the SAF shall assure that when services indicated in the treatment plan are provided by other agencies, the referral of the client shall include follow-up designed to ascertain the referral agency's progress in assisting the client.

15.11 The SAF shall maintain a written policy which prohibits alcohol, unauthorized controlled substances and/or legend drugs on the premises.

15.12 The SAF shall maintain a written policy regarding reportable, unusual incidents that involve SAF operations, treatment services or related events. The Department (treatment unit) shall be notified of all reportable incidents within two (2) business days of the occurrence on the form provided in Appendix "A."

15.13 The SAF shall maintain written policy and procedures regarding the use of urine toxicology for drug testing. These policies shall be made available to clients upon request.

15.13.1 Clients shall be afforded the opportunity to have the sample retested or evaluated by an additional testing facility licensed by the state as a laboratory (at the client's own expense). Clients shall be notified of this provision.

15.13.2 If the client so requests, positive test results that may lead to adverse action (e.g., loss of privileges) shall be confirmed by means of gas chromatography/mass spectrometry or technology recognized as being at least as scientifically accurate, at the client's own expense.

15.14 There shall be a written policy and procedure regarding child and elderly abuse and neglect issues and the reporting of these issues. This policy shall be consistent with Rhode Island laws.

15.15 The SAF shall develop and maintain a statement of discharge criteria which specifies the condition(s) under which a client is considered to be eligible for completion or ineligible for continued participation in the program.

15.16 The SAF shall develop and maintain a policy and procedure for program follow-up requirements related to treatment outcome.

15.17 The SAF shall maintain written policy regarding proper disposal of records in keeping with local, state and federal laws, in the event that a SAF ceases operation.

15.18 Where applicable, policies and procedures pertaining to the provision of services and supported by appropriate manuals and reference materials shall be established by the appropriate professional staff and approved by the administrator and the governing body. Such policies and procedures shall pertain to no less than the following:

15.18.1 the responsibility of the health professional(s) for the provision of health care services;

15.18.2 standards of practice for each health care service provided;

15.18.3 services that may and may not be provided;

15.18.4 procurement, storage and administration of drugs and medications in accordance with federal laws and R.I. Gen. Laws 21-28-1 *et seq.* ("Uniform Controlled Substances Act") and R.I. Gen. Laws 21-31-1 *et seq.* ("Food, Drug and Cosmetics Act"),

15.18.5 disposal of hypodermic needles, syringes and instruments in accordance with the requirements of *Department of Health Rules and Regulations Governing Hypodermic Needles, Syringes and Other Such Instruments and Drugs, ;*

15.18.6 disclosure of client information in accordance with federal (42 CFR, Part 2) and R.I. Gen. Laws 5-37.3-1 *et seq.* ("Confidentiality of Health Care Information Act") and

15.18.7 such other conditions as may be deemed appropriate.

15.19 A prescribed medication shall be accounted for in accordance with local, state and federal laws. Any theft, loss or spillage shall be reported immediately to the administrator of the SAF, and official incident reports shall be submitted to the Department.

15.20 Regulations in this section shall not be construed as encompassing all regulations pertaining to the handling of medications. SAFs must comply with all applicable state and federal laws.

Special Requirements for Services to Minor Clients

15.21 Residential and day-treatment programs serving minors (over thirty (30) days) shall provide, or arrange through local school districts, academic and physical education programs within fourteen (14) days of admission. All academic programs shall be approved by the Rhode Island Department of Education.

15.22 Housing, treatment and program services provided to minor clients shall include facilities separate from the adult population with the following exceptions: a) pregnant minors and b) minor children of adults undergoing residential treatment services. Such separation shall include physically separate housing as well as treatment services.

SAFs that provide residential and day treatment services may also provide services to persons under age eighteen (18) years who are either pregnant, married, or living apart from their parents or guardian(s) and are financially independent.

15.23 Parental consent shall be required of all substance abuse treatment programs that treat minors, except as otherwise provided in R.I. Gen. Laws 14-5-4 *et seq*. ("Treatment Without Parental Consent").

15.24 Residential programs shall have a written policy regarding staff responsibilities when an minor is absent without permission. The policy shall include:

a) immediate notification of the parents or legal guardian(s);

b) After the minor is absent for twenty-four (24) hours, the proper legal authorities shall be notified;

c) The client's treatment record shall reflect the elopement and appropriate notifications as they were completed.

15.25 All residential programs providing treatment to minor clients shall comply with R. I. Gen. Law 11-9-13, pertaining to the purchase, sale or delivery of tobacco products to persons under the age of eighteen (18) years.

Section 16.0 ***Laboratory Services***

16.1 Clinical laboratory services provided on the premises of the SAF shall be licensed by the state subject to the provisions of R.I. Gen. Laws 23-16.2. Testing not performed on the premises (e.g., subcontracted) shall be performed by facilities licensed in accordance with R.I. Gen. Laws 23-16.2, or by a hospital laboratory licensed in accordance with R.I. Gen. Laws 23-17-1 *et seq.* .

16.1.1 ***Human immunodeficiency virus (HIV) testing***

Facilities for drug users: All SAFs providing treatment services shall provide HIV information and offer a referral for HIV testing.

a) Every physician or health care provider attending any person for any service offered at a SAF for intravenous drug users, shall offer testing for human immunodeficiency virus (HIV) unless deemed inappropriate by the physician. All testing pursuant to this section shall be performed in accordance with R.I. Gen. Laws 23-6-17 and 18, except where federal confidentiality laws (42 CFR, Part 2) may supersede. The identity of the individuals tested under this section shall be maintained only at the site where the sample is drawn, and shall not be released except as otherwise provided by the statute.

b) Each person who is offered a test and counseling shall be provided with an "Informed Consent Form" (in accordance with RI Gen. Law 26-6-13) which he or she shall sign and date in acknowledgment of the offer.

c) All persons tested under this section shall be provided pre test and post test counseling in accordance with regulations adopted by the DOH and by RI Gen. Law 23-6-17. All persons providing the pre and/or post test counseling must have completed the training provided by the DOH office of STD's and HIV or an equivalent course.

d) The agency / physician or designee shall document referral for treatment and follow-up of all cases of HIV, HEP B or TB infection in the treatment record.

Section 17.0 ***Treatment Records***

17.1 Each SAF shall maintain a treatment record on every client receiving treatment services. The record shall include all requirements of this section and the requirements identified in the appropriate section of Part V Additional Requirements of these regulations.

17.1.1 Each satellite shall maintain a treatment record for each client receiving treatment services. The record shall include all of the requirements of this section and section 23.2 of these regulations, as appropriate.

17.1.2 The initial treatment plan shall be completed within the time frame delineated in the appropriate "Additional Requirements" section of Part V.

17.1.3 Treatment plans shall be reviewed/revised and updated according to the schedule outlined in the appropriate "Additional Requirements" sections of Part V.

17.2 The SAF treatment record shall contain documentation related to the following:

17.2.1 pertinent medical, social and drug histories and physical findings;

17.2.2 diagnostic and therapeutic orders;

17.2.3 reports of procedures, tests and findings;

a) regarding HIV testing records must be kept in accordance with RI Gen. Law 26-6-18

17.2.4 diagnostic impressions;

17.2.5 such other pertinent data as may be necessary to insure continuity of client care;

17.2.6 consent to treatment of client/family/guardian.

17.3 Each SAF shall make provisions for the appropriate release or transfer of client care information in accordance with the legal requirements of both federal and state laws and regulations.

17.4 All treatment records (either original or accurate reproductions) shall be preserved for a minimum of five (5) years, except that records of minors shall be kept for at least five (5) years after such minor shall have reached the age of 18 years.

17.5 Each SAF shall place a copy of the "Rights of Clients" statement, signed by the client, in the client's treatment record.

17.6 The client or legal guardian shall also be given a written statement concerning client's rights and responsibilities in the program which shall be signed by the client or guardian, attesting to his/her comprehension of these rights and responsibilities as explained by the staff person who shall witness the client's signature. This document shall be placed in the client's record.

17.7 The intake procedure shall involve collecting and recording at least the following information:

17.7.1 Name
17.7.2 Address, telephone number
17.7.3 Date of birth
17.7.4 Date of admission
17.7.5 Sex
17.7.6 Next of kin, legal guardian or significant other, as appropriate
17.7.7 Presenting problem or difficulty
17.7.8 Marital status
17.7.9 Type of health insurance
17.7.10 Synopsis of general impressions at time of intake, including client's attitude, appearance and general behavior
17.7.11 Any other relevant information, as appropriate.

17.8 The intake form shall be signed and dated by the individual(s) gathering the information.

17.9 Individual records shall be maintained for each client. These files shall include at least the following:

17.9.1 All information required upon admission (as described in Section 17.7 of these regulations);

17.9.2 Medical treatment history to include:

a) Prescriptions being taken at time of admission and previous six months;
b) Drug allergies, idiosyncratic reactions and/or other adverse drug effects;
c) A medical history to include medical treatment received;

17.10 The clinical summary must reflect that the placement recommendations were based on the current ASAM criteria or substantially equivalent DSA reviewed tool, and must also include the following:

a) Level of severity, for each dimension
b) DSM IV multiaxial assessment

17.11 A comprehensive initial bio-psychosocial assessment shall be developed and it shall include, but not be limited to:

17.11.1 A history of the use of alcohol and/or other drugs, including the age of onset, duration, patterns, and consequences or resultant negative effects on life areas to include:

a. Medical / physical
b. Psychological
c. Employment / education
d. Legal
e. Financial

f. Family / social
g. Recreational
h. Spiritual
i. Other matters as appropriate for treatment

17.11.2 A family history relative to substance abuse/dependency.

17.11.3 Any other relevant personal information which may include:
a) Living skills
b) Cultural issues
c) Traumas
d) Current stressors
e) Sexual concerns

17.11.4 Clinical consideration shall include a determination of the type and extent of any special examinations, tests or evaluations necessary for complete assessment.

17.11.5 For those SAFs which admit minors, the comprehensive initial assessment (of section 17.10) shall additionally include the following:

a) Assessment of developmentally age-appropriate behaviors;
b) An assessment of peer group functioning.

17.11.6 For those SAFs which admit minors, the comprehensive initial bio-psychosocial assessment (of section 17.10) shall additionally include a referral or access to an assessment of cognitive functioning, of physical maturities, and of learning disabilities which may impact on treatment, if indicated.

17.12 Information gathered in the initial bio-psychosocial assessment shall be utilized in the development of a problem list and individualized treatment plan.

17.13 The SAF shall develop and maintain a comprehensive individual treatment plan for each client served. The treatment planning process shall include the involvement of the client and clinical staff.

17.14 A major goal of the treatment plan shall be the promotion of client efforts toward recovery.

17.15 The treatment plan shall be based on the assessment of clients needs (as described in 17.10), while addressing the client's individual presenting problems (as described in section 17.11).

17.15.1 Master problems list shall be maintained to list identified problems and their current disposition which shall include, but not be limited to:

a) included in the treatment plan

b) deferred
c) referred
d) monitor through out treatment
e) problem noted no action required / wanted by client

17.16 Each individual treatment plan shall include:

17.16.1 A list of presenting problems to be addressed in treatment.

17.16.2 Short-and long term goals that relate to problems identified. Goal statements must document the desired behaviors that will demonstrate resolution of an identified problem. Goal statements must be linked logically and directly with the problem statement.

17.16.3 Treatment procedures proposed to assist the client in achieving these goals, including the type and frequency of services provided.

17.16.4 Referrals for needed services that are not provided directly by the SAF.

17.16.5 Specification and description of the strategies, indicators and/or tasks used to assess the individual's progress.

17.16.6 Time frames for the anticipated dates of achievement, completion of each goal, or for reviewing progress toward goals.

17.16.7 Service activities indicated in the treatment plan shall be followed or reassessed and modified as necessary.

17.16.8 Documentation of completion of activities as well as outcome of objectives.

17.16.9 The review and revision of treatment plans and the dates.

17.16.10 Signature of client, counselor and clinical supervisor.

In the case of the clinical supervisor carrying a case load, the treatment plan shall be co-signed by an equally qualified professional.

17.17 A specific staff member shall be assigned for each client with responsibility to assure continuity of service or case management.

17.17.1 The name of the person responsible for counseling and/or case management shall be recorded on the treatment plan.

17.18 The treatment record shall include a progress note for each session/service provided. Progress notes shall include:

17.18.1 A narrative description of the client's progress or lack of progress in each area of the treatment plan where activities have been planned;

17.18.2 Documentation of all treatment rendered to the client;

17.18.3 Description of changes in the client's condition, his/her response to treatment, and the response of significant others to the client's treatment as appropriate;

17.18.4 Activities designed to prepare client for discharge from the SAF and future utilization of appropriate supportive services;

17.18.5 The date,signature and credentials of the individual making the entry in the case record.

17.19 The treatment record shall include documentation of physician's orders for medication and treatment, change of orders and/or special treatment or evaluation.

17.19.1 For drugs prescribed following admissions, the record shall include any prescribed drug product by name, dosage and strength, as well as dates medication was administered, discontinued or changed.

17.20 Reports of any special consultations or examinations and documentation of review by appropriate staff.

17.21 Completed request for and/or “Release of Information” forms for each piece of documentation requested or released.

17.22 There shall be a written aftercare plan developed in partnership with the client before discharge. This plan shall include a description of services/activities that shall be followed after discharge. In the event that a client is faced with a crisis, the client shall be instructed regarding procedures to be followed in order to obtain assistance.

17.23 The aftercare plan shall be signed and dated by the client and the counselor.

17.24 A copy of the aftercare plan shall be provided to the client.

17.25 The record shall contain a discharge summary which summarizes information regarding the client's conditions from the time of first contact through treatment termination. The discharge summary should address the following:

17.25.1 presenting problems;
17.25.2 Initial current DSM diagnosis;
17.25.3 any significant findings;
17.25.4 Course and progress of treatment and outcomes in relation to identified problems;
17.25.5 including prognosis;

17.25.6 Final diagnosis;
17.25.7 Recommendations as stated in the continuing care plan based on current ASAM levels of care or substantially equivalent DSA reviewed tool;
17.25.8 Follow-up plans.

17.26 The discharge summary shall be completed no later than fifteen (15) days after the client's discharge from the SAF.

17.27 Coercion or force shall not be used to induce any person to remain in treatment.

17.28 The discharge summary shall include a statement which explains the circumstances under which the client discharged.

17.29 Excepting detoxification SAFs, a minimum of two (2) follow-up contact attempts shall be made within three (3) months after discharge.

_____17.29.1 if the client declines participation in follow up contacts the agency shall document this in the client record.

17.30 Documentation of both successful and unsuccessful follow-up contacts shall be recorded in the treatment record. This documentation shall include at least the following:

17.30.1 Type, date and time of contact or attempted contact;
17.30.2 Summary of contact (summary of the client's progress or regression);
17.30.3 Reason for unsuccessful contact (if applicable);
17.30.4 Signature of contact person;
17.30.5 Plan for future follow-up contacts (if applicable).

17.31 If the SAF is participating in the TOPPS II project the requirements of 17.29 and 17.30 will be waived for the duration of the TOPPS II project.

17.32 All record entries shall be legibly written in pen or typed, and shall be dated and contain the original signature of the recorder.

17.33 The record system shall be organized and maintained in a standard fashion so that pertinent data can be easily accessible, readable, and understood by a reviewer, as well as for administrative and professional purposes and in compliance with all state and federal laws.

17.34 No information regarding the client or his/her involvement with the SAF shall be requested from, or disclosed to, another agency or individual without the client's (and/or legal guardian's if appropriate) written authorization or as otherwise permitted by federal confidentiality laws (42 CFR Part 2) or regulations.

A completed release of/request for information form shall be used for this purpose. This form shall include:

17.34.1 The client's name and date of birth;
17.34.2 The name and address of the agency or individual requesting or releasing the information;
17.34.3 The name and address of the agency or individual for whom the information is being requested, or to whom the information is being released;
17.34.4 Exactly what information is being requested or released;
17.34.5 The reason the information is being released or requested;
17.34.6 The date, event or condition upon which the consent expires;
17.34.7 Date signed;
17.34.8 Client's signature or signature of legal guardian;
17.34.9 Signature of witness, or legal guardian;
17.34.10 Signature of attorney, as applicable;
17.34.11 A statement that the consent for release or transfer of information may be withdrawn by the client;
17.34.12 A statement that information disclosed, released or transferred shall not be given, sold, transferred or in any way disseminated unless otherwise permitted by federal regulations.

17.35 There shall be evidence of ongoing random review of active client records by the clinical supervisor or other qualified staff member.

17.36 There shall be written documentation of the results of the client's physical examination. (See Part V "Additional Requirements" sections for physical examination documentation criteria).

17.36.1 If client has undergone a physical examination by a physician, physician assistant or nurse practitioner within one (1) year prior to admission, the results of this examination shall be considered sufficient for fulfilling this requirement. The provisions of this section do not apply to Residential Rehabilitation, Medical Detoxification, Outpatient Detoxification and Narcotic Treatment levels of care.

17.36.2 Laboratory evaluation, including liver function tests, shall be required annually, at a minimum, for any active client with evidence of parenteral drug abuse within the past year, as determined by the examining physician.

17.37 ***Human immunodeficiency virus (HIV) testing:*** All SAFs providing treatment services shall provide HIV information and/or referral for HIV testing.

17.38 The SAF shall have a written policy statement in compliance with all applicable federal and state laws regarding the administration of all prescription medications used by clients.

Section 18.0 ***Medical Equipment***

18.1 Medical equipment and supplies for the reception, appraisal, examination, treatment and observation of clients shall be determined by the amount, type and extensiveness of services provided.

PART IV *PHYSICAL PLANT AND EQUIPMENT*

Section 19.0 *Physical Plant*

19.1 Each SAF shall be designed and equipped to facilitate the reception, examination and treatment of clients in accordance with prevailing regulations and to safeguard the dignity and privacy of clients to the extent consistent with client care management and efficient administration.

Satellite Facilities

19.2 The satellite SAF shall meet all of the requirements of this section, section 20.0 ("Environmental Maintenance") and 20.7 ("Waste Disposal") herein, as applicable.

19.2.1 Any SAF delivering services at a satellite facility shall ensure that the satellite complies with all of the applicable requirements of the Fire Safety Code.

Section 20.0 *Environmental Maintenance*

20.1 The SAF shall be maintained and equipped to provide a sanitary, safe and comfortable environment with all furnishings in good repair, and the premises shall be kept free of hazards.

20.2 Written policies and procedures shall be established to assure a comfortable, safe and sanitary environment and appropriate lighting throughout the SAF.

20.3 Appropriate equipment and supplies to clean the SAF shall be maintained in a safe, sanitary condition.

20.4 Hazardous cleaning solutions, compounds and substances shall be labeled, stored in a safe place and kept in an enclosed section separate from other cleaning materials.

20.5 The SAF shall comply with all applicable federal, state and local laws, codes, rules and regulations relative to health, drug control, fire safety, building, minimum housing and zoning.

20.5.1 ***Residential Facilities***

i) Any SAF (residential facilities) accommodating fewer than twelve (12) residents shall conduct fire drills at a minimum of six (6) times per year. At least fifty percent (50%) of these drills shall be obstructed drills, as defined by the state fire/safety regulations.

ii) Any SAF residential facility accommodating twelve (12) or more residents shall conduct fire drills twelve (12) times per year.

1. Fire drill documentation shall be maintained and shall include:

a) name of person conducting the drill
b) date/time of drill
c) amount of time taken to evacuate the building
d) type of drill (obstructed/unobstructed)
e) record of problems and steps taken to correct them.

iii) For a residential facility that provides food service, the SAF shall be required to meet any requirements for food handling required by R. I. Gen. Laws 21-27-1 *et seq*. ("Sanitation in Food Establishments")

a) The SAF shall ensure that resident meals comply with any special dietary needs or requirements, as ordered by a physician.

20.6 The SAF shall develop, maintain and post a written evacuation plan to areas of refuge or from the SAF in the event of fire or any other type of disaster or emergency.

20.7 ***Waste Disposal***

20.7.1 ***Medical Waste:*** Medical waste, as defined in the *Rules and Regulations Governing the Generation, Transportation, Storage, Treatment, Management and Disposal of Regulated Medical Waste* (DEM-DAH-MW-01-92, April 1994) of the Rhode Island Department of Environmental Management, shall be managed in accordance with the provisions of the aforementioned regulations.

20.7.2 ***Other Waste:*** Wastes which are not classified as infectious waste, hazardous wastes or which are not otherwise regulated by law or rule may be disposed in dumpsters or load packers provided the following precautions are maintained:

a) Dumpsters shall be tightly covered, leak proof, inaccessible to rodents and animals, and placed on concrete slabs preferably graded to a drain. Water supply shall be available within easy accessibility for washing down of the area. In addition, the pick-up schedule shall be maintained with more frequent pick-ups when required. The dumping site of waste materials must be in sanitary landfills approved by the Department of Environmental Management.

b) Load packers must conform to the same restrictions required for dumpsters and, in addition, load packers shall be:

1) high enough off the ground to facilitate the cleaning of the underneath areas of the stationary equipment; and

2) the loading section shall be constructed and maintained to prevent rubbish from blowing from said area site.

PART V *ADDITIONAL REQUIREMENTS*

Section 21.0 ***Residential Rehabilitation Services***

This section applies to all residential rehabilitation services. These programs must also comply with the General Regulations cited above.

21.1 ***Personnel***

21.1.1 The SAF shall employ at least one full-time registered nurse per shift, duly licensed in Rhode Island, with experience in substance abuse counseling or services.

21.1.2 The SAF shall employ, either directly or on a consultant basis, the services of a medical director who shall be duly licensed to practice medicine in Rhode Island.

21.1.3 The SAF shall employ, either directly or on a consultant basis, the services of a qualified professional to provide mental health evaluations.

21.2 ***Health Services***

21.2.1 SAF clients shall participate in individual counseling no less than two (2) days per week.

21.2.2 SAF clients shall participate in group counseling no less than five (5) days per week, unless an individual's participation is deemed detrimental to him/herself, or to others in the group.

21.2.3 Family counseling shall be provided for clients on an as-needed basis and documented in the treatment record.

21.2.4 Vocational or occupational counseling shall be provided on an as-needed basis.

21.3 ***Treatment Record***

21.3.1 The treatment record shall be reviewed/revised and updated at least weekly or as issues arise.

21.3.2 Progress notes related to individual and/or group therapy must be documented in the record for each session attended.

21.3.3 There shall be written documentation of the results of the client's physical examination within three (3) days after admission.

21.3.4 There shall a be documented discharge summary reflecting actual treatment progress recorded in the client's record within five (5) days after discharge (See section 17.24 for requirements).

Section 22.0 *Extended Residential Care Services*

This section applies to all extended residential care services. These services must also comply with all applicable sections of the General Regulations.

22.1 *Health Services*

22.1.1 Clients shall participate in individual counseling as required by the treatment plan, but at a minimum of at least once a week for one month, bi-weekly for three months and once a month thereafter.

22.1.2 Clients shall participate in group counseling as required by the treatment plan, but at a minimum of at least twice weekly, unless an individual's participation is deemed detrimental to him/herself, or to others in the group.

22.2 *Treatment Record*

22.2.1 All clients shall have a physical examination prior to admission to the residence. This shall be documented in the treatment record within sixty (60) days after admission.

a) If the client has undergone a physical examination by a physician, physician assistant or nurse practitioner within one (1) year prior to admission, documentation of the results of this examination shall be considered sufficient for fulfilling this requirement.

22.2.2 The initial assessment shall be developed in conjunction with the social history within five (5) days of admission to the program. However, in treatment facilities for minor clients, the social history shall be developed within twenty-one (21) days of admission to the program.

22.2.3 The initial treatment plan shall be developed within thirty (30) days of admission to the program.

22.2.4 Treatment plans shall be reviewed/revised and updated at least every sixty (60) days during the client's enrollment in the program, or as new treatment issues arise.

Section 23.0 *Outpatient Drug-Free Services*

This section applies to all outpatient drug-free services.
These services must also comply with all applicable sections of the General Regulations.

23.1 *Health Services*

23.1.1 The SAF shall have a policy stipulating that counseling services are available at least one (1) evening per week or one (1) weekend day.

23.1.2 Such services are provided in regularly scheduled sessions of usually fewer than 9 contact hours per week. Outpatient services should be designed to treat the individuals level of illness severity and to achieve permanent changes in an individuals alcohol or other drug using behavior.

23.1.3 Clients participating in day/evening treatment services shall participate in no less than one (1) individual counseling session per week. Clients participating in day/evening treatment services shall participate in group counseling on a daily basis unless an individual's participation is deemed detrimental to him/herself or to others in the group.

23.2 *Treatment Record*

23.2.1 A written bio-psychosocial assessment shall be developed within 30 days of admission to the SAF and placed in the treatment record.

23.2.2 An initial written treatment plan shall be developed within 30 days of admission to the program and placed in the treatment record.

23.2.3 Written treatment plans shall be reviewed/revised and updated at least every ninety (90) days.

a) For day/evening treatment clients, the initial treatment plan shall be developed within 14 days of admission to the SAF. (If a client has been referred from an inpatient-residential rehabilitation service, the referring agency's treatment plan may be utilized as the basis for treatment.)

b) For day/evening treatment clients, treatment plans shall be reviewed at least weekly during the client's enrollment in the program, and revised as goals are accomplished or new treatment issues arise. Such reviews shall be documented in the progress notes and on the treatment plan.

23.2.4 For clients participating in outpatient services, there shall be written documentation of the results of the client's physical examination within sixty (60) days.

a) If a client has undergone a physical examination by a physician, physician assistant or nurse practitioner within one (1) year prior to admission, the results of this examination shall be considered sufficient for fulfilling this requirement.

23.2.5 For clients participating in day/evening treatment services, documentation of the physical examination shall be included in the record within thirty (30) days after admission.

a) If a client has undergone a physical examination by a physician, physician assistant or nurse practitioner within one (1) year prior to admission, the results of this examination shall be considered sufficient for fulfilling this requirement.

Section 24.0 ***Opioid Treatment Programs***

This section applies to all public or private narcotic treatment and maintenance programs. These programs must also comply with all applicable sections of the General Regulations and with 42 CFR Part 8 (DHHS/SAMHSA, DEA Regulations), and R. I. Gen. Laws 21-28-1 *et seq*. (Uniform Controlled Substance Act), R. I. Gen. Laws 21-28.2-1 *et seq.* (Drug Abuse Control Act), R. I. Gen. Laws 21-28.3-1 *et seq.* (Drug Abuse Reporting System), Rhode Island General Laws 5-19-1 *et seq.*(Pharmacy Statute), and Rhode Island State Methadone Authority. Programs shall reference the State Methadone Treatment Guidelines/TIP 1 (Treatment Improvement Protocols series/CSAT)

Opioid treatment programs (OTPs) shall use only opioid agonist treatment medications that are approved by the Food and Drug Administration, and the Cosmetic Act (21 U.S.C. *355)* for use in the treatment of opioid addiction.

24.1 ***Organization & Management***

24.1.1 Prior to admission to an OTP, all client information shall be entered into the Department's Substance Abuse Database Central Registration System. The required information shall include:

a) the patient's initials (first, middle, last);
b) date of birth;
c) last four digits of the Social Security number;
d) anticipated date of admission;
e) gender.

24.1.2 To prevent patients from being enrolled in more than one OTP, the Central Registry shall be notified immediately of transfers and discharges. The information shall be treated as confidential and not released, except for treatment purposes or as required by law. Information made available to programs must be held as confidential. In emergencies, the SAF medical director or other qualified physician shall make the clinical judgment on when methadone treatment is initiated.

a) In the event of the state Central Registry being inoperable the OTP's programs are to obtain appropriate releases and check with each of the other OTP's prior to admitting any patient.
b) The documentation of such checks are to be noted in the client case record and when the state system is again operable the OTP must submit the data necessary to clear the client through the Central Registry.

24.1.3 The SAF shall have a policy for drug testing. The policy shall include the following:

a) All patients shall have a drug test upon admission. A specimen positive for opiates is not necessary for admission to a OTP, if other criteria have been satisfied.

b) All required drug tests shall include a screening for the following substances: opiates, methadone, cocaine, benzodiazepines, as well as substances prevalent in the community.

1. Any additional drug tests ordered at the discretion of the agency can be specific to the patients treatment needs.

c) The SAF drug testing policy and procedure is approved by the Department.

d) Random drug testing shall be collected no less than monthly while a patient remains in treatment.

e) Specimens shall be collected in a manner that minimizes falsification and stored in a secure place to avoid substitution.

f) Testing facilities shall be licensed by the state of Rhode Island pursuant to R.I. Gen. Laws 23-16.2-1 *et seq.* and qualified to do drug testing.

g) Results of drug testing shall not be used in a punitive manner, but rather, serve as one factor in making treatment decisions.

h) Each SAF shall have its own protocol regarding the increased frequency of drug testing, as ordered by SAF physicians.

24.1.5 All female patients of childbearing potential shall be tested for pregnancy before admission to LAAM Maintenance Treatment, medical documentation of client inability to become pregnant shall be in the client record. Pregnancy testing shall be performed monthly thereafter. (Use of LAAM is not approved for clients during pregnancy).

24.1.6 The SAF shall have a written policy describing procedures to be implemented when a client needs "Courtesy Dosing" while enrolled in an approved treatment program.

24.1.7 Arrangements for Courtesy Dosing shall be made in advance, whenever possible, by SAF staff and approved by the medical director. Documentation of same shall become part of the client's record.

a) The transferring facility may give the patient up to a fourteen (14) day take-home supply with a written physician's order. Arrangements for longer periods of Courtesy Dosing shall be made with the approved program closest to the patient.

24.2 *Personnel Requirements*

24.2.1 *Medical Director:*

Each SAF shall have a designated medical director who has the responsibility for administering all medical services. She/he shall be licensed to practice medicine in the State of Rhode Island, have Rhode Island Department of Health Controlled Substance Registration and be DEA registered. The medical director or other authorized SAF physician shall assume the following responsibilities:

a) documenting evidence of current physiological narcotic addiction;

b) ensuring that a medical evaluation and medical history have been completed;

c) ensuring that the appropriate laboratory studies have been performed;

d) signing or counter-signing, as appropriate, all medical orders;

e) reviewing and signing treatment plans annually.

24.2.2 *Nursing Supervisor:*

Each OTP shall have a registered nurse (RN) who shall be responsible for the general supervision of the nursing staff. The nurse shall be licensed to practice in the state of Rhode Island and shall participate in ongoing professional development in the area of substance abuse.

24.2.3 *Nursing Personnel:*

All employed nurses shall be licensed to practice in Rhode Island. Nurses shall have a valid license to practice, without stipulations, as confirmed by the Department of Health, Division of Professional Regulation. There should be appropriate staffing to ensure that patients receive nursing services during hours of operation and are consistent with best practice standards.

24.2.4 *Counselor:*

To ensure that appropriate rehabilitative services are being provided, a SAF shall have caseloads that follow best practice standards. Caseloads may vary due to patient acuity and intensity of treatment as well as availability of Patient Support Staff to assist the counselor and patient with collateral issues.

24.2.5 ***Patient Support Staff:***

To ensure coordination and continuity of care, assist in negotiating and procuring needed services to high-risk population.

a) The OTP shall abide by section 11.3.1

b) The remaining fifty percent (50%) shall consist of a comes combination of Patient Support Staff and those actively engaged in the process of meeting requirements of section 11.3.1 and supervised as appropriate.

c) OTPs will not be required to comply with 11.3.2 if Patient Support Staff are utilized in the staffing pattern.

24.2.6 ***Pharmacist:***

All pharmacists employed by a SAF shall be licensed by the State of Rhode Island and must be authorized by the SAF to dispense methadone / LAAM All federal laws and regulations that pertain to the handling of methadone/LAAM shall apply in these regulations.

24.3 ***Treatment Record***

24.3.1 Each patient shall have written treatment plans reviewed/revised and updated every ninety (90) days during the first two (2) years of services and twice (2) per year after the second continuous year.

24.3.2 Patients shall receive an annual physical exam by a SAF physician. Physicians' orders for dosing schedules and treatment plans shall be renewed no less than annually by the physician at the time of the annual physical.

24.3.3 An initial treatment plan shall be completed within the first thirty (30) days of admission into the SAF.

24.3.4 Documentation of the patient's drug testing results shall be maintained in the treatment record and utilized in making treatment decisions.

24.4 ***Health Services***

24.4.1 Rehabilitative counseling services (individual, group and family) shall be provided by SAF staff and be consistent with the patient's treatment plan.

24.4.2 A minimum of one (1) hour of individual counseling shall be provided monthly (in one or two sessions) and shall be documented in the client's treatment record for the first year of treatment.

a) Patients admitted for detoxification services (short and long term) shall be provided two (2) hours of individual counseling and shall be documented in the patient's record.

b) Thereafter a medical/clinical determination shall be made, and documented in the patient's record, as to the type and frequency of counseling necessary. Any patient who is participating in group counseling on ***at least*** a monthly basis shall be seen ***at***

least every ninety (90) days in individual counseling, for ***at least*** one hour. A patient who is not participating in group counseling shall be seen ***at least*** every thirty (30) days in individual counseling.

c) Patient who have initiated "Medically Supervised Withdrawal" shall be re-evaluated for frequency of counseling sessions and that assessment be documented in the patient record.

24.4.3 Admission requirements shall include:

a) Documentation of a one-year history of opiod addiction for patient's eighteen (18) years of age and over. Exceptions may be granted by the Program Director for applicants who have been released from prison or chronic care facilities, are HIV positive, pregnant, and/or previously treated patient's.

b) Patients under eighteen (18) years of age, the program must verify a minimum of two (2) prior short term detoxifications or drug free treatment episodes in a twelve (12) month period and must obtain parental or legal guardian's consent.

c) No persons under sixteen (16) years of age can be admitted to a narcotic treatment program unless the program has received prior written approval of the admission from the State Methadone Authority.

24.4.4 If the patient is readmitted to a program within three (3) months of discharge, the results of prior medical and laboratory exams may be used for up to twelve (12) months from the date of the last physical examination.

24.4.5 The SAF shall develop a written policy that describes the procedure to be used to identify properly each client before methadone/LAAM is dispensed.

24.4.6 A physician or physician extender shall determine, and document in writing, the initial dose and schedule to be followed. This information shall be communicated to the licensed medical staff supervising the dispensing of methadone/LAAM. Initial doses shall not exceed thirty milligrams (30) unless a physician documents that the client requires a higher dose.

24.4.7 Prior to administration of LAAM, the OTP shall follow recommendations of the pharmaceutical insert. ie interpretive EKG.

24.4.8 Patient's transferring from another program may receive their daily dose as ordered, after verification from medical personnel to medical personnel from the transferring agency. Before the initial dose is dispensed, clients shall complete all screening and admission procedures, except in an emergency situation or in a courtesy dosing situation (of section 24.1.7), which shall be documented in the treatment record.

a) The medical record shall be transferred when the patient transfers between affiliated clinics. Every attempt shall be made and documented regarding

dosing history, lab work, and toxicology. As well as treatment plans and discharge summaries when patients transferred from non-affiliated clinics.

24.4.9 Narcotic drugs shall only be dispensed by licensed professionals authorized by law to do so. A dose shall not be administered until a client is identified and assessed to be medically and clinically appropriate.

24.4.10 The dosage to be dispensed shall be verified with the current dosage ordered. Ingestion shall be observed by the person who administered the methadone/LAAM, who shall sign in the appropriate program records by the end of the day.

24.4.11 Methadone is to be dispensed in oral form and in one (1) dose per container. LAAM is to be dispensed in liquid form in single doses.

24.4.12 A patient's methadone/LAAM may be withheld when the SAF medical staff determines that administration of the dose would not be medically or clinically appropriate at the time. The incident shall be documented in the treatment record.

24.4.13 ***Take-home privileges:***

SAFs shall develop a policy that will ensure compliance with federal and state regulations before take-home methadone privileges are granted. The policy shall include at least the following:

a) At least a two (2) month probationary period has been observed when daily clinic visits are required and clients have satisfactorily met the requirements of the program.

b) After two (2) months, no fewer than six (6) clinic visits with one (1) take-home doses per week may be permitted.

c) After three (3) months, may be decreased (3) to five (5) clinic visits weekly with two (2) take-home doses per week permitted.

d) After six (6) months, the client may be permitted to reduce attendance to three (3) visits weekly with no more than two (2) consecutive day supply of medication.

e) After one (1) year the patient may be permitted to reduce attendance to two (2) visits weekly and given no more than three (3) consecutive day supply of medication

f) After two (2) years, the patient may be permitted to reduce clinic attendance to once (1) weekly and receive no more than a six (6) day take-home supply of medication.

g) After three (3) years, the patient may be permitted to reduce clinic attendance to two (2) visits monthly and receive no more than fourteen (14) day supply of medication.

h) After four (4) years, the client may be permitted to reduce clinic attendence to once (1) monthly.

i) In an emergency situation or severe illness, patient's may be given up to a ten day supply of take home doses. The reason must be recorded in the treatment record and be based on the reasonable judgment of the SAF physician.

j) Indication in the treatment record of a safe home environment and that instruction regarding safety (including child safety measures and storage) has been provided to and documented for each client prior to the initiation of take-home privileges. Documentation that each client has obtained an agency approved locked box for storage of take home medication.

k) The client has no untreated alcohol or other drug dependency / abuse.

l) Take-home containers shall be labeled with the following information:

* Patient's Name
* Name and Amount of Drug
* Directions for Use, including route (IE, by mouth)
* Date Issued and Date to be Taken
* Program's Name and Address
* Program's Telephone Number

m) Child -proof caps shall be used on all take-home bottles containing methadone.

n) The SAF physician shall document in the treatment record the rationale for take-home privileges.

o) Patient's shall return all take-home containers on their next day of clinic attendance. Bottles shall be inspected to ensure they are coming from the appropriate client during the appropriate time period prior to a patient's receiving his/her subsequent dose. The agency is to have a policy regarding non return of take home bottles and the consequences are to be determined, and documented, by the program taking into consideration at least the following :

A. the patient's treatment history at the agency
B. repeated occurrences
C. reason for damage to label or client inability to produce container

p) An OTP shall revoke take-home privileges if it is deemed inappropriate by the SAF's physician.

q) Take-home doses are not allowed during long or short-term methadone detoxification, with the exception of holidays.

r) Patient's may contest a revocation of take-home privileges through the grievance procedure cited in section 12.2 herein.

s) For short and long-term detoxification from opiates, it is required that the patient be under observation while ingesting the methadone / LAAM daily with the exception of approved holidays and emergency closings, for the duration of the detoxification treatment.

t) An OTP must maintain a "Diversion Control Plan" as part of the quality assurance program.

24.4.14 ***Discontinuance of Methadone Use***

a) Withdrawal from methadone/LAAM shall be available to all patients who request it.

b) The determination to withdraw voluntarily from methadone/LAAM maintenance treatment shall be left to the patient and the judgment of the SAF's physician. The withdrawal schedule shall be determined on an individual basis and completed under the observation of SAF staff.

c) OTP's shall develop a written procedure establishing the criteria for involuntary termination from treatment. This procedure shall be made available to all patients upon admission and repeated at the time of impending termination. When on-site withdrawal is determined to be undesirable. A clinic assisted transfer to an appropriate SAF shall be made.

d) OTP's shall develop a written procedure establishing standards for against medical advice withdrawal. The withdrawal schedule shall be determined on an individual basis and completed under the supervision of the SAF staff.

e) OTP patient's who have completed a voluntary withdrawal from methadone/LAAM shall be eligible for aftercare counseling through drug-free outpatient services.

f) Patient's who have successfully completed the medically supervised withdrawal or detoxification phase and are being transferred to an outpatient drug-free program at the same SAF, shall be transferred to "opiod treatment programs aftercare" status in the Client Information System at the Division of Substance Abuse no later than seven (7) days after the client's last dose.

g) Patient's who complete a medically supervised withdrawal shall be given priority for re-admission within thirty (30) days of leaving treatment.

h) A program shall not admit a patient for more than two detoxifications treatment episodes in one year. Patients with 2 or more unsuccessful detox episodes should be evaluated by the OTP physician for other forms of treatment.

24.4.14 ***Security Requirements:***

In addition to the security requirements of the DEA Regulations Governing Narcotic Treatment Programs (Parts 1301 - 1307 and 42 CFR part 2) and R.I. Gen. Laws 21-28-1 *et seq.* ("Controlled Substance Act"), the following requirements must be met:

a) Access to electronic alarm areas where drug stock is maintained shall be limited to a minimum number of authorized personnel. Each employee shall have his/her own individual code which shall be erased upon termination. There shall be a list maintained stating who has access to the stock / safe and dispensing station and what type of access they have.

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

1) Name of substance;
2) Strength of substance;
3) Date of reconstitution;
4) Lot number;
5) Reconstituted expiration date or manufacture date, whichever is shorter

All stored poured doses shall have readily available the following information:

1) Name of substance;
2) Strength of substance;
3) Date of reconstitution;
4) Lot number;
5) Reconstituted expiration date or manufacture date, whichever is shorter

c) 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.

d) Following the date the initial methadone/LAAM inventory occurs, 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. Inventory shall contain:

1) Name and address of SAF;
2) Date of inventory;
3) Opening or closing of business day;
4) Quantity of methadone/LAAM on hand, amount used, amount received;
5) Total accounted for;

6) Signature of person performing the inventory

e) The Department shall be notified of any theft, suspected theft, or any loss of methadone/LAAM, including spillage. The form RI Report of Unusual Incidents shall be completed on each occurrence and sent to the Rhode Island DMHRH along with a photo copy of DEA form 106. Copies of both the RI Report of Unusual Incidents and DEA form 106 shall also be sent to the Department.

f) The disposal of unused controlled substances shall be done in accordance with procedures provided by Federal DEA Regulations (Part 1307.21) and the state of Rhode Island Department of Health. This process shall be conducted quarterly at minimum and shall be strictly adhered to.

g) All narcotic treatment programs shall be open seven (7) days per week with the exception of all officially observed state holidays.

Section 25.0 ***Medical Detoxification Services***

This section applies to all Medical Detoxification services. These services must also comply with all applicable sections of the General Regulations. Medical Detoxification services are provided in a hospital or suitably equipped medical setting.

25.1 ***Organization & Management***

25.1.1 The SAF shall have a written agreement with a nearby hospital for transferring clients in cases of medical emergencies.

25.1.2 There shall be a written physician-approved detoxification protocol or standing detoxification orders for each substance for which the program detoxifies clients.

25.1.3 The SAF shall have a written policy for involuntary discharge procedures which shall include a requirement that all clients shall be informed of the program's rules and regulations, and shall sign a statement that he/she knows and understands the rules and regulations.

25.1.4 There shall be a written policy for any client who leaves detoxification treatment against the advice of staff. The client shall be informed of the risks of leaving treatment prematurely, sign an Against Medical Advice Form, and the form shall be witnessed by a staff member.

a) If the client refuses to sign the Against Medical Advice Form the SAF staff shall document this on the aforementioned form and sign.

25.1.5 The SAF shall have established written admission criteria.

25.2 ***Personnel***

25.2.1 The staff shall be trained and be competent in the medical management and supervision of the detoxification from alcohol and drugs. Documentation of staff training shall be retained on file and be available for review.

25.2.2 Staffing shall provide twenty-four (24) hour awake supervision, and the SAF shall be opened seven (7) days a week. Adequate staffing levels shall be maintained to admit, treat, and discharge clients.

25.2.3 ***Physician:***

The SAF shall have on staff a supervising physician who has the responsibility for oversight of all medical and pharmaceutical procedures. He/she shall be licensed to practice medicine in the state of Rhode Island.

25.2.4 ***Nursing Supervisor:***

The SAF shall have a designated registered nurse who shall be responsible for the general supervision of the nursing staff. She/he shall be licensed to practice nursing in the state of Rhode Island, and shall participate in ongoing professional development in the area of substance abuse. Documentation of such training shall be retained in each employee's personnel file.

25.2.5 ***Nursing Personnel:***

There shall be no less than one (1) licensed nurse per thirty (30) inpatient clients being treated in ~~a~~ detoxification. The number of licensed nursing staff shall be commensurate with the number of clients being served. All nursing staff shall be licensed to practice nursing in the state of Rhode Island.

25.2.6 ***Counseling Personnel:***

To ensure that the appropriate rehabilitative services are provided, the client shall be assigned a primary counselor who will follow the client's progress during detoxification. Such progress shall be documented in the client's treatment record.

25.2.7 ***Auxiliary Personnel:***

Staffing shall be appropriate to ensure the safety of the client and staff. They shall have the necessary training and be competent to recognize signs and symptoms of chemical dependency.

25.3 ***Treatment Record***

25.3.1 Clients shall remain in a medical detoxification program for the period of time deemed medically necessary and documented by the SAF's physician.

25.3.2 A complete medical history and physical examination shall be performed and documented on each client within twenty-four (24) hours of admission.

25.3.3 A bio-psychosocial assessment shall be completed and documented within seventy-two (72) hours of admission.

25.3.4 An initial treatment plan addressing short-term detoxification goals shall be completed within seventy-two (72) hours of admission. This plan may be reviewed/revised and updated when/if the client is readmitted. This plan shall be documented in the client's treatment record.

Section 26.0 *Social Setting Detoxification Services*

This section applies to all Social Setting Detoxification Services. Services in this section must also comply with the General and Residential regulations as they apply to the service being rendered. Social Setting Detoxification programs shall be limited to persons who require non-medical alcohol/drug detoxification services.

26.1 *Organization & Management*

26.1.1 The SAF shall have operational procedures to admit clients twenty-four (24) hours a day, seven (7) days a week.

26.2 *Personnel*

26.2.1 All direct care staff shall have training in and have the ability to recognize the need for medical evaluation / referral associated with trauma, illness and detox.

26.2.2 Staffing shall be provided for twenty-four (24) hour awake supervision, and the SAF shall be open seven (7) days a week. Adequate staff shall be on duty at all times to admit, treat, and discharge clients.

26.3 *Treatment Record*

26.3.1 A complete medical history with current established ASAM, or substantially equivalent DSA reviewed, criteria in place to determine if a client needs to be referred for a physical examination or further medical treatment shall be performed and documented on each client.

26.3.2 A psychosocial assessment shall be completed and documented within seventy-two (72) hours of admission.

26.3.3 An initial treatment plan addressing short-term detoxification goals shall be completed within seventy-two (72) hours of admission.

Section 27.0 ***Outpatient Detoxification Services***

This section applies to all Outpatient Detoxification services, but does not include narcotic maintenance/detoxification programs. These services must also comply with all applicable sections of the General Regulations. Outpatient detoxification programs shall provide drug/alcohol detoxification services on an outpatient basis.

27.1 ***Organization & Management***

27.1.1 There shall be a written, physician-approved detoxification protocol or standing detoxification orders for each substance for which the program is prepared to detoxify clients.

27.1.2 The program shall have a written policy that documents an affiliation agreement with a nearby community hospital to provide support services in case of a medical emergency related to detoxification.

27.2 ***Personnel***

27.2.1 All medical, nursing and counseling staff shall have training in and have the ability to recognize medical conditions associated with trauma, illness and detox.

27.2.2 ***Medical Director:*** Each program shall have a designated medical director who has the responsibility for administering all medical services. This physician shall be licensed to practice medicine in the state of Rhode Island.

27.2.3 ***Registered Nurse:*** A registered nurse (RN) duly licensed in the state of Rhode Island shall be on site to access individual clients who are being detoxified on an outpatient basis.

27.2.4 To ensure that the appropriate rehabilitative services are provided, the client shall be assigned a primary counselor who will follow the client's progress during detoxification. Such assignment shall be documented in the treatment record.

27.3 ***Health Services***

27.3.1 Upon admission, a complete physical examination as well as the required blood work shall be completed before medication is administered to a client. Clients who have been determined by the program physician to be physiologically in need of detoxification from alcohol/drugs according to current ASAM, or substantially equivalent DSA reviewed, criteria may be admitted for outpatient detoxification. The client shall be assessed by the SAF physician to be at minimal risk of severe withdrawal syndrome.

27.3.2 Medical protocols shall be established under the direction of the SAF's medical director. These protocols shall be dispensed by the SAF physician or other authorized licensed medical staff person. All medication shall be dispensed by the established protocol schedules and administered on a daily basis.

27.4 ***Treatment Record***

27.4.1 A psychosocial assessment shall be completed and documented within seventy-two (72) hours of admission.

27.4.2 An initial treatment plan addressing short-term detoxification goals shall be completed within seventy-two (72) hours of admission.

PART VI *PRACTICES & PROCEDURES, CONFIDENTIALITY & SEVERABILITY*

All of the provisions of Part VI herein shall also apply to the operation of a satellite SAF.

Section 28.0 *Variance Procedures*

28.1 The licensing agency may grant a variance either upon its own motion or upon request of the applicant from the provisions of any rule or regulation in a specific case if it finds that a literal enforcement of such provision will result in unnecessary hardship to the applicant and that such a variance will not be contrary to the public interest, public health and/or health and safety of clients.

28.2 A request for a variance shall be filed by an applicant in writing, setting forth in detail the basis upon which the request is made.

28.2.1 Upon the filing of each request for variance with the licensing agency, and within thirty (30) days thereafter, the licensing agency shall notify the applicant by certified mail of its approval or in the case of a denial, a hearing date, time and place may be scheduled if the SAF appeals the denial and in accordance with the provisions of section 29.0 herein.

Section 29.0 *Rules Governing Practices and Procedures*

29.1 All hearings and reviews required pursuant to these rules and regulations shall be held in accordance with the provisions of R.I. Gen. Laws 42-35-1 *et seq.*

Section 30.0 *Confidentiality*

30.1 Disclosure of any health care information, to the Department, relating to individuals shall be subject to the provisions of both State and Federal statutes and regulations.

Section 31.0 *Severability*

31.1 If any provision of the rules and regulations herein or the application thereof to any SAF or circumstances shall be held invalid, such invalidity shall not affect the provisions or application of the rules and regulations which can be given effect, and to this end the provisions of the rules and regulations are declared to be severed.

APPENDIX "A"
STATE OF RHODE ISLAND & PROVIDENCE PLANTATIONS
DEPARTMENT OF MENTAL HEALTH, RETARDATION AND HOSPITALS
CONFIDENTIAL REPORT OF INCIDENT
LICENSED SUBSTANCE ABUSE FACILITY

Agency _____

Type of Facility (Mark [X] One):

_____Detox_____Residential_____Outpatient_____Narcotic Treatment

_____Day / Evening Treatment

(Mark [X] One): _____Client_____Staff Name/MIS#: _____

Date of Incident: ____/____/____Time of Incident: ____/____/____ AM/PM (Circle)

Day of Week: (Circle) Sun Mon Tues Wed Thur Fri Sat

Location of Incident: (Include address)_____

_____
__

Nature of Incident: (Mark "X")

1._____Serious Accidental Injury
2._____Sudden Death
3._____Suicide
4._____Assault
5._____Medication Error
6._____Serious Injury
7._____Suicide Attempt
8._____Fire
9._____Other _____
10.____Sentinel Event:_____

Notified: (Mark "X")

1. _____Police - State/Local (Circle)
2. _____Fire Department
3. _____Rescue Squad (treatment related)
4. _____Physician
5. _____Medical Examiner
6. _____Hospital Emergency Room
7. _____Other_____
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Description of incident and immediate action taken in response to incident; include name of persons involved, including witnesses.

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Does this incident require follow up? Yes_____ No_____

Results of Follow up/Investigation:_____

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Process Improvement Plan (When Applicable)

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Signature of Person Reporting Date

_____
Signature of Witness Date

Complete this form and send to the Division's of Substance Abuse and Licensing within 2 business days. If follow up is required send the initial report and then upon completion of the follow up send the appropriate documentation with a copy of the original report attached.

Division of Licensing
14 Harrington Road
Bldg. 52 - Barry Hall
Cranston, RI 02920

Division of Substance Abuse
14 Harrington Road
Bldg. 52 - Barry Hall
Cranston, RI 02920

APPENDIX "B"

LEVELS OF CARE LICENSED

RESIDENTIAL FACILITIES	**SERVICES ALLOWED UNDER LICENSE**
Detoxification	Medical Detox Services | Social Detox Services | Outpatient Detox | Day Treatment | Outpatient
Residential Rehabilitation (Medical care/support)	Medical Detox Services | Social Detox Services | Outpatient Detox | Day Treatment | Outpatient
Extended Residential (Non-medical)	Long Term Care Services | Transitional Care Services | Day Treatment | Outpatient
Outpatient FACILITIES	**SERVICES ALLOWED UNDER LICENSE**
Outpatient Drug Free	Outpatient Detox Services | Day Treatment Services | Outpatient
OPIOD TREATMENT FACILITIES	**SERVICES ALLOWED UNDER LICENSE**
Narcotic Treatment	Opiod Treatment Services | Opiod Detox | Day Treatment Services | Outpatient Services

[3]Services other than those allowed under the level of care will require certification.
Facilities providing services to minors shall comply with all applicable requirements.
Satellite facilities are limited to outpatient drug-free services only.