WEST VIRGINIA
SECRETARY OF STATE
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ADMINISTRATIVE LAW DIVISION

Form #3

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OFFICE WEST VIRGINIA
SECRETARY OF STATE

NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE
AND
FILING WITH THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

AGENCY: Department of Health and Human Resources TITLE NUMBER: 64

CITE AUTHORITY: W. Va. Code 16-1-4 and 27-9-1

AMENDMENT TO AN EXISTING RULE: YES ____ NO X

IF YES, SERIES NUMBER OF RULE BEING AMENDED: ____

TITLE OF RULE BEING AMENDED: ____

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: 90

TITLE OF RULE BEING PROPOSED: Regulation of Opioid Treatment Programs

THE ABOVE PROPOSED LEGISLATIVE RULE HAVING GONE TO A PUBLIC HEARING OR A PUBLIC COMMENT PERIOD IS HEREBY APPROVED BY THE PROMULGATING AGENCY FOR FILING WITH THE SECRETARY OF STATE AND THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE FOR THEIR REVIEW.

Martha Yeager Walker
Authorized Signature

BRIEF SUMMARY OF THE RULE

REGULATION OF OPIOID TREATMENT PROGRAMS

64CSR90

Summary: This proposed legislative rule is a new rule, authorized by an act of the West Virginia Legislature during Legislative year 2004 at W.Va. Code §16-1-4. The rule governs programs providing medication-assisted opioid treatment services in West Virginia. The new rule contains a description of licensing procedures; required qualifications for staff; procedures for quality assurance; criteria for recordkeeping, admissions and treatment, including take-home (unsupervised) medications; and detoxification and discharge procedures. The purpose of this rule is to set specific standards to govern opioid treatment programs in order to allow the Department of Health and Human Resources to better monitor and regulate medication-assisted treatment of opioid dependent citizens of West Virginia.

For further information contact: Sheila Emerson Kelly, Program Manager, Office of Health Facility Licensure and Certification, Bureau for Public Health, Department of Health and Human Resources, telephone (304) 558-0488, 1 Davis Square, Suite 101, Charleston, West Virginia, 25301.

Copies of the proposed rule may be obtained from the website of the West Virginia Secretary of State at www.wvsos.com or interested parties may call the Administrative Law Division of the Office of the Secretary of State at (304) 558-6000.

STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE PROPOSED RULE

REGULATION OF OPIOID TREATMENT PROGRAMS

64CSR90

This new rule was developed at the request of the 2004 West Virginia Legislature in order to better regulate the proliferation of medication-assisted opioid treatment programs in West Virginia. Since 2001, the number of programs licensed by the state of West Virginia as Behavioral Health Centers (64CSR11) has grown from zero to eight with at least five more in development and pending approval by the West Virginia Health Care Authority in the coming year. More than 4,000 individuals are being treated by the licensed methadone programs at the present time. The behavioral health regulations do not adequately address the specific treatment needs of the opioid dependent population and the potential dangers of medication-assisted treatment. This rule brings West Virginia standards into compliance with federal standards for care, allows the Department of Health and Human Resources to ensure that programs are in compliance with both state and federal standards of care, and in some cases, provides standards which are more stringent than those provided by the federal government in order to meet local demands for increased attention to the health and safety of consumers and the public at large.

QUESTIONNAIRE

(Please include a copy of this form with each filing of your rule: Notice of Public Hearing or Comment Period; Proposed Rule, and if needed, Emergency and Modified Rule.)

DATE: July 25, 2005

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM:(*Agency Name, Address & Phone No.*) Office of Health Facility Licensure and Certification
Bureau for Public Health
Department of Health and Human Resources
1 Davis Square, Suite 101
Charleston, WV 25301
Telephone: (304) 558-0050

LEGISLATIVE RULE TITLE: Regulation of Opioid Treatment Progams

1. Authorizing statute(s) citation W.Va Code 16-1-4 and 27-9-1

2. a. Date filed in State Register with Notice of Hearing or Public Comment Period:

June 8, 2005

b. What other notice, including advertising, did you give of the hearing?

The proposed rule was distributed to all licensed behavioral health centers providing opioid treatment services; the West Virginia Association for Behvioral Healthcare Providers; the West Virginia Methadone Advocacy Project; and other interested parties.

c. Date of Public Hearing(s) ***or*** Public Comment Period ended:

July 8, 2005

d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.

Attached X No comments received _____

e. Date you filed in State Register the agency approved proposed Legislative Rule following public hearing: (be exact)

July 25, 2005

f. **Name, title, address and <u>phone/fax/e-mail numbers</u>** of agency person(s) to receive all *written correspondence* regarding this rule: (Please type)

Aimee Jackson, Paralegal
Office of Health Facility Licensure and Certification
Bureau for Public Health
Department of Health and Human Resources
1 Davis Square, Suite 101
Charleston, WV 25301
Telephone: (304) 558-0687 Fax (304) 558-2515
E-mail: AimeeJackson@wvdhhr.org

g. **<u>IF DIFFERENT</u> FROM ITEM 'f'**, please give **Name, title, address and phone number(s)** of agency person(s) who wrote and/or has responsibility for the contents of this rule: (Please type)

Sheila Emerson Kelly, Program Manager
Office of Health Facility Licensure and Certification
Bureau for Public Health
Department of Health and Human Resources
1 Davis Square, Suite 101
Charleston, WV 25301
Telephone: (304) 558-0488

3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:

a. Give the date upon which you filed in the State Register a notice of the time and place of a hearing for the taking of evidence and a general description of the issues to be decided.

N/A

b. Date of hearing or comment period:

N/A

c. On what date did you file in the State Register the findings and determinations required together with the reasons therefor?

N/A

d. Attach findings and determinations and reasons:

Attached N/A

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Regulation of Opoid Treatment Programs

Type of Rule: ___x___ Legislative _____ Interpretive _____ Procedural

Agency: Health and Human Resources

Address: 1 Davis Square, Suite 101

Charleston, WV 25301-1799

Phone Number: 558-0488 Email: sheilakelly@wvdhhr.org

Fiscal Note Summary

Summarize in a clear and concise manner what effect this measure will have on costs and revenues of state government.

Currently, there are eight (8) opoid treatment programs operating in West Virginia. The Health Care Authority has applications for eight (8) more programs and potentially an additional eight (8) programs could be added in coming years. Upon full implementation the Department estimates that this would result in twenty-four (24) annual surveys lasting five (days) each and fifty (50) complaint investigations lasting two (2) days each per year.

The Department estimates the cost to provide oversight of this activity to be $75,584 the first year and $72,084 thereafter. These costs consist of one (1) FTE Health Facility Surveyor and a 0.2 FTE Program Manager position, employee benefits and travel expenses.

The Department does not believe that licensure revenue from this activity would be sufficient to cover the cost of this activity. Renewal fees are based on the average number of patients enrolled per day: $250 per year for under 500 patients; $500 per year for between 500 and 1,000 patients, and $750 per year for clinics averaging enrollment over 1,000 patients. In 2006 the Department's Office of Health Facility Licensure and Certification will license eight clinics. The Department projects that three of those clinics will see under 500 patients per year, generating renewal revenue of $750, three will see between 500 and 1,000 patients, generating $1,500 in revenue and two will see over 1,000 patients, generating $1,500 in revenue.

According to the Health Care Authority, an additional eight clinics may open in 2006 for a total of 16 clinics. Half of those clinics will see under 500 patients, generating $2,000 in revenue; six will see between 500 and 1000 patients, generating $3,000 in revenue and two will see over 1,000 patients, generating $1,500 dollars in revenue. In 2007, it is estimated that the state will peak at 24 clinics. Of these half (12) will see under 500 patients, generating $3,000 in revenue, ten will see 500 to 1,000 patients, generating $5,000 in revenue and two will see over 1,000 patients generating $1,500 in revenue for the year. Therefore, the total estimated revenue by year is projected to be: FY2006 $3,750, FY2007 $6,500 and thereafter $9,500.

Fiscal Note Detail

Show over-all effect in Item 1 and 2 and, in Item 3, give an explanation of Breakdown by fiscal year, including long-range effect.

Effect of Proposal	Fiscal Year		
	2005 Increase/Decrease (use"-")	2006 Increase/Decrease (use"-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	75,585	72,085	72,085
Personal Services	60,085	60,085	60,085
Current Expenses	12,000	12,000	12,000
Repairs and Alterations			
Equipment	3,500		
Other			
2. Estimated Total Revenues	3,750	6,500	9,500

3. Explanation of above estimates (including long-range effect):

Please include any increase or decrease in fees in your estimated total revenues.

Personal Services: 1.0 FTE Health Facility Surveyor @ $41,891, 0.2 FTE Program Manager @ $42,598 * 0.2 = $8,520 for a total personal Services of $50,411. Employee Benefits: Personal Services * 19.19% (FICA, PERS, WC) = $9,674. **TOTAL Personal Services and Benefits of $60,085.**

Current Expense: Travel $12,000 (Average travel cost/surveyor/year. Equipment: Laptop Computer and Portable Printer $3,500. **TOTAL Estimated Cost $75,585.**

Ongoing costs for subsequent years are based on current level less equipment purchase.

Revenue Projections: FY2006 $3,750 (3 @ $250 = $$750, 3 @ $500 = $1,500, 2 @ $750 = $1,500). **FY2007 $6,500** (8 @ $250 = $2,000, 6 @ $500 = $3,000, 2 @ $750 = $1,500). **Thereafter $9,500** (12 @ $250 = $3,000, 10 @ $500 = $5,000, $=2 @ $750 = $1,500).

Memorandum

Please identify any areas of vagueness, technical defects, reasons the proposed rule **would not** have a fiscal impact, and/or any special issues **not** captured elsewhere on this form.

Date	Agency	Authorized Representative
July 25, 2005	Department of Health and Human Resources	Martha Yeager Walker Secretary

PUBLIC COMMENTS AND DEPARTMENT RESPONSES

REGULATION OF OPIOID TREATMENT PROGRAMS, 64CSR90

Comments to the Regulation of Opioid Treatment Programs (64CSR90) proposal were received from four individuals:

1) Raymona Kinneberg from Bill J. Crouch & Associates;
2) Dr. Michael McNeer, who served on the committee which developed the rule;
3) Ellen Valli, Program Director of the Martinsburg Institute and also a member of the committee; and
4) Dann White, a representative of the West Virginia Methadone Advocacy Project.

Response: Ms. Kinneberg's comments were accurate and primarily technical and minor changes were made in the rule to address her concerns.

Comments: Dr. McNeer's comments were more substantive and are summarized as follows:

- No take-home (unsupervised) doses during the first ninety days of treatment and more restrictive take-home approval thereafter;
- Increases in take-home doses should be strictly dependent on clean urine screens;
- Any "dirty" urine screens result in return to entry level unsupervised medications;
- Medical directors of Opioid Treatment Programs should have at least one year of experience in Opioid Treatment Programs;
- Each clinic should have a medical director (presumably full time);
- Short-term detoxification should be defined as thirty days from admission rather than thirty days from stabilization;
- Physician and consumer should, without exception, have face-to-face contact before first dose;
- All urine drug screens should test for marijuana and barbiturates;
- More frequent urine drug testing; and
- Ban on medication units.

Response: Dr. McNeer's comments were presented to the office previously and many of his issues had already been addressed in the final rule. In general, he was satisfied with the rule as it was finalized, but continues to have the concerns listed above.

To require clinics to provide no take-home medications would mean that the clinics would have to be in operation seven days per week. All of the clinics currently operate six days per week and have done so for years. The Department feels that it would be unfair to change the operating procedures of those clinics to such a degree, particularly since the federal requirements enable even more liberal take home privileges.

The clinics have asked that reductions in take-home privileges because of "dirty" urines be considered to be a clinical decision, made by the physician and the primary counselor, based on a variety of patient behaviors including clinic attendance, prior history of illicit urines, progress in

achieving treatment objectives and so on. The Department will monitor this issue through the survey process and if necessary provide regulatory direction to "outliers".

Medical directors have proven impossible to obtain for clinics, even on a part-time basis. The CRC Group has been recruiting for a year for a physician for the Beckley Treatment Center. Unfortunately, the regulations as they are written are the only realistically achievable standards for physician qualifications. The Department agrees with Dr. McNeer regarding the desirability of the standard he recommends, but believes that requiring such a standard would be unduly burdensome for providers.

Short-term detoxification is defined in the rule as being thirty days from time of stabilization. The Department felt that rigid requirement that the patient be detoxified within thirty days regardless of withdrawal and discomfort during substitution of the opioid substance would trigger renewed use of illicit substances and respectfully recommends against this except in cases of court-ordered or administrative withdrawal.

The Department agrees that face-to-face contact between physician and patient prior to initial dose is by far the best practice. The clinics have asked to be able to initiate dosing on an emergency basis with telephone authorization by the clinic physician after full intake by an appropriate health professional. They argue that they may lose patients to withdrawal and continued addiction if they cannot immediately address patient need. The rule requires that exceptions to the face-to-face admission process be reviewed by an internal admissions committee for appropriateness. The Department intends to generate a survey protocol which will monitor these admissions and the committee reviews so that they remain at a level of less than 10% of all admissions per facility.

Urine drug screens are required by the rule in greater frequency than that required by the federal regulations. There must be a compromise between patient cost and efficacy of detection of illicit use. Any clinic is welcome to exceed the requirements based on patient behavior and compliance with treatment. Marijuana screens are an issue of debate in most states with regard to the consequences of positive urine screens. The Department elected to require three random screens per year for marijuana. Clinics may also screen for barbiturates at any time, based on patient symptomatology and community patterns of abuse. Again, cost and efficacy must be weighed.

The Department agrees with Dr. McNeer with regard to medication stations, but has been assured by the Health Care Authority that these would be considered an expansion of service and therefore reviewable with input from the Bureau for Behavioral Health and Health Facilities and the Office of Health Facility Licensure and Certification. The Department believes that control of the spread of medication stations can be addressed in that forum.

Comments: The comments of Ms. Valli, Program Director, Martinsburg Institute, were as follows:

- The requirement for master's level staff or an experienced bachelor's level staff to perform psychosocial intakes is burdensome. Ms. Valli feels that this "puts our most experienced staff doing lengthy intake tasks. In addition, how would new staff ever be able to gain the experience needed to perform assessments"; and
- The requirement for an advisory board with representation from the community and patients and staff is burdensome and duplicates their executive council which is made up of the clinical directors of five programs that meets monthly.

Response: The Department believes that the intake process is a crucial moment in the patient's contact with the clinic. At this point individuals who are trying to "game the system" are identified and weeded out and individuals with co-occurring mental health problems are earmarked for referral for appropriate treatment. Therefore, the most qualified staff must be deployed. The Department has no problem with bachelor's level staff spending a year sitting in on intake interviews in order to gain the experience necessary to perform them independently, but is not willing to develop a regulatory process by which the least experienced staff is performing the clinical work requiring the most sophistication and expertise.

The advisory board is designed to provide independent advice and input to the governing body of the clinic. The advisory board is made up of community and patient representatives in order to expand the points of view available to the governing body and to "keep it honest" in treating honorably and respectfully with the consumers and community it serves. It cannot be replaced with a committee of representatives of the governing body. This defeats the function of the committee as it is designed and intended.

Comments: Lastly, the comments of Dann White, member of the West Virginia Methadone Advocacy Project (Advocacy Project), were extensive and not all related to issues which could be considered regulatory. Those that were relevant included:

- The Advocacy Project believes that every patient should be entitled to a patient advocate in cases of administrative discharge and withdrawal and in cases of grievances;
- The Advocacy Project has construed the regulations to require that counselors have bachelor's level minimum education;
- The Advocacy Project believes that the requirement that each program have a diversion control plan is not useful in controlling diversion and that clinics should have the ability to turn suspected diversion over to law enforcement for investigation;
- The policy of clinics to discharge patients who are unable to pay the daily rate is unfair and unethical;
- The regulations are excessive and duplicative of federal regulation, discouraging providers from locating in West Virginia; and
- Disaster plans as they are currently formatted in some clinics are inadequate.

Response: While the Department believes that every patient deserves the right to be heard and to appeal unfavorable decisions, the Department does not wish to prevent clinics from taking

prompt administrative action when necessary to control diversion or other misuse of medications. Each clinic is required by the regulations to have an advisory committee which reviews all patient grievances and administrative discharges. The committee is deliberately not composed of governing body members, but is made up of patient, staff and community representatives. This provides a system of review and "checks and balances". Each program is also required to have an effective grievance procedure which patients are encouraged to use and which have rights of appeal to state and federal authorities. The Department believes these rules are sufficient to guarantee patient rights.

The regulations allow Certified Addictions Counselors to be employed as primary counselors. The requirements for the Certified Addictions Counselors enable individuals without bachelor's' degrees to obtain certification. Therefore, the Advocacy Project has misunderstood the regulation.

Diversion control plans are required by federal regulation and accreditation standards. Mr. White cites several actions that can be taken by a clinic to control diversion. These need to be viable parts of a clinic's diversion control plan. Each clinic must be able to credibly demonstrate a concern for the safety of patients and the community. Clinics cannot turn the name of suspected "diverters" over to law enforcement, because such disclosure is prohibited by federal rules regarding confidentiality.

The Department freely admits that state regulations are duplicative of federal regulations in many instances. This gives the State the ability to enforce federal standards and to make some standards more stringent in response to community concerns of health and safety. The federal government performs reviews of 1% of all clinics per year and requires accreditation of all clinics. The Department believes that the State must have the ability to regulate clinics on a much more immediate and frequent schedule and, further, the State must have the ability to perform investigations of complaints, using appropriate regulations to do so. The vast majority of states have rules and regulations specific to Opioid Treatment Programs and the citizens of West Virginia, through the Legislative process, have demanded such rules in West Virginia. In most instances, if a clinic is in compliance with federal regulations and accreditation requirements, little to no additional paperwork or burden will be created by compliance with 64CSR90.

TITLE 64
LEGISLATIVE RULES
DIVISION OF HEALTH
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

SERIES 90
REGULATION OF OPIOID TREATMENT PROGRAMS

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TABLE OF CONTENTS

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LEGISLATIVE RULES
DIVISION OF HEALTH
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SERIES 90
REGULATION OF OPIOID TREATMENT PROGRAMS

§64-90-1. General.

1.1. Scope. -- This rule establishes a mechanism for regulating the provision of opioid treatment services and sets forth minimal standards for State approval of opioid treatment providers.

1.2. Authority. -- W. Va. Code §§16-1-4 and 27-9-1.

1.3. Filing Date. --

1.4. Effective Date. --

1.5. Purpose -- This rule shall govern all aspects of the regulation of opioid treatment programs in West Virginia.

§64-90-2. Application and Enforcement.

2.1. Application. -- This rule applies to all for-profit programs and not-for-profit programs approved by the state of West Virginia to provide opioid treatment services. These programs are exempt from Division of Health rule, "Behavioral Health Centers Licensure," 64CSR11, as long as the services offered remain solely those described within this rule. If additional services are provided, the opioid treatment program shall comply with applicable licensure laws and rules.

2.2. Enforcement. -- This rule is enforced by the secretary of the Department of Health and Human Resources. The secretary shall designate an office of the department to act in his or her stead.

2.3. Adoption of Other Standards. -- In addition to the standards set forth in this rule, "Certification of Opioid Treatment Programs," 42 CFR 8, are hereby adopted in their entirety by reference: Provided, That to the extent there is a conflict between federal regulations or standards and the standards set forth in this rule, the more stringent standard applies.

§64-90-3. Definitions.

3.1. Administrative Withdrawal. -- Involuntary withdrawal or administrative discharge from pharmacotherapy, usually relatively brief.

3.2. Administrator. -- Individual designated by the governing body to be responsible for the day-to-day operation of the opioid treatment program.

3.3. Admissions Committee. -- Committee consisting of program administrator or his or her designee, the medical director or his or her designee and a senior counselor. Purpose of the committee is to review and track exceptions to program admissions policies and procedures.

3.4. Adverse Event or Incident. -- An event involving immediate threat to the care or safety of an individual, either staff or patient; or the possibility of serious operational or personnel problems; or the potential to undermine public confidence in the treatment program.

3.5. Advisory Council. -- Designated group of individuals representative of staff, patients and the community appointed to serve in a non-managerial advisory capacity to the governing body.

3.6. Complaint. -- A verbal or written statement made by a patient, family member or community member alleging inadequate or inappropriate service on the part of the program, typically filed either with the program or a state agency.

3.7. Comprehensive Biopsychosocial Assessment. -- Medical and biopsychosocial evaluation of a patient completed within thirty days of admission, evaluating all aspects of the individual's physical, psychological and adaptive functioning.

3.8. Designated State Oversight Agency. -- The agency or office of state government identified by the secretary to provide regulatory oversight on behalf of the state of West Virginia; responsible for licensing, monitoring and investigating complaints or grievances regarding opioid treatment programs.

3.9. Detoxification. -- The dispensing of an opioid agonist treatment medication in decreasing doses to the patient to alleviate adverse physical or psychological effects incident to withdrawal from the continuous or substantial use of an opioid drug and as a method of bringing the patient to a drug-free state within such period.

3.10. Diversion Control Plan. -- A required plan developed by the program to minimize the diversion of methadone or other opioid treatment medications to illicit use.

3.11. Governing Body -- The person or persons identified as being legally responsible for the operation of the opioid treatment program; may be a board, a single entity or owner, or a partnership.

3.12. Grievance. -- A written or oral complaint filed by a patient alleging inadequate or inappropriate treatment by the program.

3.13. Induction. -- Initial treatment of an opioid addicted patient with opioid agonists in order to suppress signs/symptoms of withdrawal and drug cravings; usually referring to gradual

increase in agonist therapy until such time as symptoms are regularly and reliably suppressed/controlled.

3.14. Informed Consent to Treatment. -- Written verification that the patient has been informed of the advantages and disadvantages of aspects of the treatment provided to a patient and that the patient agrees to the treatment.

3.15. Initial Assessment. -- The first medical and brief psychosocial interview or interviews with a patient that focus on the individual's eligibility or need for treatment and provide indicators for initial dosage level should admission be deemed appropriate.

3.16. Initial Plan of Care. -- The treatment plan developed in conjunction with the patient describing the proposed focuses of efforts by staff and patient to stabilize the patient and suppress the signs/symptoms of withdrawal from opioids during the first thirty days of program participation.

3.17. Interdisciplinary Team. -- The patient, a representative of medical staff and the primary counselor; may include family members if desired by the patient. Purpose is to approve and coordinate the plan of care for the patient.

3.18. Maintenance Dose. -- The level of opioid replacement therapy considered to consistently suppress signs or symptoms of withdrawal and drug cravings for individuals with opioid addiction; usually represents the end of the induction period. Is individualized for each patient and may gradually change over time.

3.19. Medical Director. -- The physician licensed within the state of West Virginia identified as having authority over and responsibility for all medical aspects of the treatment process.

3.20. Medical Withdrawal. -- The gradual voluntary and therapeutic withdrawal of the patient from opioid replacement therapy, agreed upon by patient and staff; may occur against medical advice.

3.21. Medication-Assisted Treatment. -- The use of medications in conjunction with a clinical program of services such as individual and family therapy to treat individuals with addictions to opioids.

3.22. Methadone. -- An opioid agonist used as replacement therapy for opioids in the addicted patient.

3.23. Opioid Addiction. -- Compulsive seeking and use of prescription or illicit narcotics in spite of negative physical and/or personal consequences.

3.24. Opioid Agonists. -- Substances that bind to and activate the opiate receptors resulting in analgesia and pain regulation, respiratory depression and a wide variety of behavioral changes.

3.25. Opioid Treatment Program. -- Programs licensed by the state of West Virginia and certified by the United States Drug Enforcement Administration and Substance Abuse and Mental Health Services Administration to provide medication-assisted therapy for individuals addicted to opioids.

3.26. Opioids. -- A class of medication or drugs used to deal with pain; sometimes referred to as narcotics; includes morphine, codeine, oxycontin/oxycodone, heroin and others; operate by blocking the transmission of pain messages to the brain. Chronic use can result in addiction or physical dependence.

3.27. Orientation. -- The introduction of the patient to the policies and procedures of the opioid treatment program and to the theory and process of medication-assisted therapy.

3.28. Patient. -- Person served; consumer; patient; individual receiving treatment.

3.29. Physician. – An individual licensed to practice medicine under W.Va. Code §30-3 by the West Virginia Board of Medicine or under W.Va. Code §30-14 by the West Virginia Board of Osteopathy.

3.30. Physician Extender. -- Medical staff person other than a physician, functioning within his or her scope of practice to provide medical services to the patient. An approved physician extender has met the requirements for his or her scope of practice and has completed the training program recommended and approved by the medical director. Licensed practical nurses are excluded from consideration as physician extenders although they may work within the program in other capacities.

3.31. Plan of Care. – The treatment plan developed and coordinated by the interdisciplinary team; follows the completion of the initial plan of care, usually after thirty days; reviewed at regular intervals, no less than every ninety days.

3.32. Plan of Correction. -- The written description of the actions the program intends to take to correct and prevent the reoccurrence of violations of rule and regulation identified by the designated state oversight agency during a survey or complaint investigation.

3.33. Plan of Education. -- The approved continuing education plan for the physician, counselor or physician extender to attain competence in the field of opioid treatment.

3.34. Primary Counselor. -- The individual designated by the program to serve as the patient's consultant and advisor on a regular basis; a member of the patient's interdisciplinary team.

3.35. Program Physician. -- A physician designated and approved by the medical director to prescribe and monitor medication-assisted treatment for individuals with opioid addiction. The medical director may serve as the program physician.

3.36. Relapse Prevention Plan. -- A plan of action developed by the patient in conjunction with the counselor to help the patient to deal with situations or environmental stimuli that were previously associated with abuse of opioids or other inappropriate substances.

3.37. Secretary. -- The secretary of the West Virginia Department of Health and Human Resources or his or her designee.

3.38. State Authority/State Methadone Authority. -- The individual designated as the state's coordinator for the development and monitoring of narcotic treatment programs; serves as a liaison with the appropriate federal agencies.

3.39. Take-Home Medication. -- Medication provided for unsupervised use based upon the patient's demonstrated compliance with the plan of care; must be recommended by the primary counselor and approved by the medical director or program physician.

3.40. Toxicology Screen. -- Urine drug screens or other approved medical screening processes designed to monitor and evaluate the patient's initial need for treatment and subsequent progress in treatment.

3.41. Variance. -- A formal agreement between the state authority or designated oversight agency and the program that allows the program to comply with the intent of a regulatory requirement in a manner not permitted by the wording of the requirement; may not be obtained based solely on the inability to achieve compliance.

3.42. Waiver. -- A formal, time-limited agreement between the designated oversight agency and the program that suspends a rule or regulation for a specific situation so long as the health and safety of patients are better served in the situation by suspension of the rule than by enforcement.

§64-90-4. State Administrative Procedures.

4.1. General Licensure Provisions.

4.1.a. Before establishing, operating, maintaining or advertising a medically-based opioid treatment program within the state of West Virginia, a program shall first obtain from the secretary a license authorizing the operation.

4.1.b. If the secretary determines not to issue a license, the applicant shall be notified.

4.1.c. A license is valid for the program named in the application and is not transferable.

4.1.d. An expired or otherwise invalid license shall be surrendered to the secretary upon written demand.

4.2. License Application.

4.2.a. An application shall identify the service location and office or offices operated by the program.

4.2.b. Initial applications shall be received by the secretary not less than thirty days and not more than sixty days prior to the initiation of services.

4.2.c. Renewal applications shall be received by the secretary not less than sixty days prior to the expiration of the current license.

4.2.d. Amended license applications shall be required by the secretary if there is a change in the geographic location of a service or program.

4.2.e. An application for an initial or renewal license shall identify the governing body.

4.2.f. Applications for an initial or renewal license shall be accompanied by a non-refundable licensure fee in the following amounts:

4.2.f.1. Initial licensure fees shall be set at $250;

4.2.f.2. Programs with an average daily total census of fewer than five hundred patients shall remit a fee of $250 for each annual renewal;

4.2.f.3. Programs with an average daily total census of five hundred to one thousand patients shall remit a fee of $500 for each annual renewal;

4.2.f.4. Programs with an average daily total census of more than one thousand patients shall remit a fee of $750 for each annual renewal; and

4.2.f.5. The annual fee shall be adjusted on June 1st of each year to correspond with increases in the consumer price index.

4.2.g. After a complete application with required fee for a renewal license has been received, the existing license shall not expire until the new license has been issued or denied.

4.3. Issuance.

4.3.a. An inspection shall be made before an initial, renewal or provisional license is issued.

4.3.b. Following an application review and an onsite inspection or inspections with approval of subsequent plans of correction as needed, the secretary shall, if there is substantial compliance with this rule, issue a license in one of three categories:

4.3.b.1. An initial license valid for six months from the date of issuance shall be issued to programs establishing a new service found to be in substantial compliance on initial

review with regard to policy, procedure, facility and recordkeeping regulations.

4.3.b.2. A provisional license shall be issued when a program seeks a renewal license and is not in substantial compliance with this rule but does not pose a significant risk to the rights, health and safety of a consumer. It shall expire not more than six months from date of issuance, and shall be consecutively reissued only upon action of the secretary, unless the provisional recommendation is that of the state fire marshal.

4.3.b.3. A renewal license shall be issued when a program is in substantial compliance with this rule and shall expire not more than one year from date of issuance.

4.4. License Amendment.

4.4.a. The program shall notify the secretary thirty days prior to a change in the name or substantial nature of the program and shall apply for license amendment.

4.5. Waiver.

4.5.a. The secretary may grant a waiver or variance to the provisions of this rule if its application clearly would be impractical and if any alternate arrangements are not detrimental to the health or safety of the consumers or employees of the program. The secretary may provide consultation in obtaining compliance with this rule.

§64-90-5. Governance.

5.1. Before construction or extensive renovation begins, an applicant shall submit to the secretary for approval a complete set of drawings and specifications for the architectural, structural and mechanical work.

5.2. All extensively renovated and new structures shall meet current Americans with Disabilities Act standards.

§64-90-6. Health and Safety.

6.1. To carry out the intent of this rule, the secretary requires inspections by authorized representatives.

6.2. Inspections shall include, but are not limited to:

6.2.a. Observation of service delivery;

6.2.b. Review of life safety and environmental conditions;

6.2.c. Review of clinical and administrative records; and

6.2.d. Interviews with patients, with their consent, staff and administrators.

6.3. Each licensed program shall be inspected annually. All programs shall be accredited as required by the federal agency responsible for oversight of opioid treatment programs. The program shall submit a copy of the results of the accreditation survey to the secretary and to the state authority when they become available.

6.4. The program shall comply with any reasonable requests from the secretary to have access to the service, staff, patients (with their permission) and records of the operation of the program or services provided to patients.

6.5. Within ten working days of completion of an inspection, the secretary shall issue a report.

6.6. Based upon a program's previous substantial compliance with this rule, an onsite inspection is not always required for issuance of an amended license.

§64-90-7. Complaint Investigation.

7.1. Any person may file a complaint with the secretary alleging violation of applicable laws or rules by a program. A complaint shall state the nature of the complaint and the program by name.

7.2. The secretary may conduct unannounced inspections of programs involved in a complaint proceeding and any other investigations necessary to determine the validity of a complaint.

7.3. At the time of the investigation, the investigator shall notify the administrator of the reason for the complaint.

7.4. Within ten working days of the investigation, the secretary shall provide to the program a written report of the results of the investigation along with any violations.

7.5. The secretary shall provide to the complainant a description of any corrective action the program shall be required to take and of any disciplinary action the secretary may take.

7.6. The names of a complainant and of any consumer involved in the complaint or investigation, and any information that could reasonably lead to their identification, shall be kept confidential and shall not be disclosed without their written consent. Before disclosure of investigative information to the public, such identifying information shall be deleted.

7.7. If a complaint becomes the subject of a judicial proceeding, nothing in this rule prohibits the disclosure of information that would otherwise be disclosed in judicial proceedings.

7.8. The secretary may suspend or revoke a license for violating the prohibitions of this

section.

§64-90-8. Reports and Records.

8.1. The secretary shall keep on file a report of any inspection or investigation.

8.2. A report shall specify the deficiency and the provision of the rule it violates.

8.3. Information in reports or records is available to the public except:

8.3.a. As specified in this section regarding complaint investigations;

8.3.b. If it is information of a personal nature from a consumer or personnel file; or

8.3.c. If it is information required to be kept confidential by state or federal law.

8.4. A report made public shall also state whether a plan of correction has been submitted to or approved by the secretary.

§64-90-9. Plans of Correction.

9.1. Within ten working days after receipt of the inspection report, the program shall submit to the secretary for approval a written plan to correct all deficiencies that are in violation of this rule, unless a variance is requested by the program and granted by the secretary. The plan shall specify:

9.1.a. Action taken or procedures proposed to correct the deficiencies and prevent their reoccurrence;

9.1.b. Date of completion of each action taken or to be taken; and

9.1.c. Signature of the head of the governing body or his or her designee.

9.2. The secretary shall approve, modify or reject the proposed plan of correction in writing. Modifications may be made by the program in conjunction with the secretary.

9.3. The secretary shall state the reasons for rejection or modification of any plan of correction.

9.4. When the secretary rejects a plan of correction, a revised plan shall be submitted within ten working days upon receipt of the rejection by the program.

9.5. The program shall immediately correct a violation that severely risks the health or safety of a consumer or other persons.

9.6. The secretary shall determine if corrections have been made.

§64-90-10. Waivers and Variances.

10.1. The secretary may grant any waivers or variances to regulations contained herein so long as:

10.1.a. The waiver or variance serves the best interests of patient safety and quality of care; and

10.1.b. The waiver or variance is written, approved by the secretary, and reviewed at least annually by the designated state oversight agency.

§64-90-11. Penalties.

11.1. The secretary may deny the program's application for licensure or licensure renewal; revoke or suspend a license; and/or order an admissions ban or reduction in consumer census for one or more of the following reasons:

11.1.a. The secretary makes a determination that fraud or other illegal action has been committed;

11.1.b. The program has violated federal, state or local law relating to building, health, fire protection, safety, sanitation or zoning;

11.1.c. The program conducts practices that jeopardize the health, safety, welfare or clinical treatment of a consumer;

11.1.d. The program has failed or refused to submit reports or make records available as requested by the secretary; or

11.1.e. A program has refused to provide access to its location or records as requested by the secretary.

11.2. If a license has been revoked, the secretary may stay the effective date of the revocation if the program can show that the stay is necessary to ensure appropriate referral and placement of consumers.

§64-90-12. Administrative Due Process.

12.1. Any person aggrieved by an order or other action by the secretary based on this rule may request in writing a hearing by the secretary in accordance with the Division of Health rule, "Rules of Procedure for Contested Case Hearings and Declaratory Rulings," 64CSR1, a copy of which may be obtained from the secretary of State.

§64-90-13. Designation of State Authority and Powers and Duties of State Authority.

13.1. The secretary of the Department of Health and Human Resources shall designate an individual or agency within the department to serve as the state authority to facilitate oversight and technical assistance to opioid treatment programs

13.2. The powers and duties of the state authority shall include, but not be limited to, the following:

13.2.a. Facilitating the development and implementation of rules, regulations, standards and best practice guidelines to assure the quality of services delivered by opioid treatment programs;

13.2.b. Acting as a liaison between relevant State and federal agencies;

13.2.c. Reviewing opioid treatment guidelines and regulations developed by the federal government;

13.2.d. Assuring delivery of technical assistance and informational materials to opioid treatment programs as needed;

13.2.e. Performing both scheduled and unscheduled site visits to opioid treatment programs in cooperation with the identified state oversight office when necessary and appropriate;

13.2.f. Consulting with the federal government regarding approval/disapproval of requests for exceptions to federal regulations, where appropriate;

13.2.g. Reviewing and approving exceptions to federal and state dosage policies and procedures;

13.2.h. Receiving and referring consumer appeals and grievances to the designated state oversight agency when appropriate; and

13.2.i. Working cooperatively with other relevant state agencies to determine the service need in the location of a proposed program.

§64-90-14. Federal Certification, Approval by State Authority and State Licensure.

14.1. All individuals or organizations providing medically-based opioid treatment services shall be approved by the state authority and appropriately licensed by the designated state oversight agency of the state of West Virginia: Provided, That physicians certified by the Substance Abuse and Mental Health Services Administration to provide opioid treatment in a private arena with approved medications shall not be required to be approved by the state authority.

14.2. The designated state oversight agency and state authority shall evaluate each entity applying to provide opioid treatment services to assure that the entity is in compliance with applicable state and federal standards

14.3. In order to be eligible for licensure, an opioid treatment program must comply with all regulations, provisions and standards contained in "Certification of Opioid Treatment Programs," 42 CFR Part 8.

14.4. Hospitals licensed under 64CSR12 and behavioral health facilities licensed under 64CSR11 providing opioid treatment services shall be subject to licensing requirements contained within this rule in addition to relevant licensing requirements as specified by the secretary.

§64-90-15. Administrative Organization.

15.1. Each program shall identify a governing body.

15.2. The governing body shall be responsible for designation of an administrator. The administrator shall be responsible for the day-to-day operation of the program in a manner compliant with the laws and regulations of the United States Department of Health and Human Services, Drug Enforcement Administration and the state of West Virginia.

15.3. Duties of the administrator shall include:

15.3.a. Development of policies and procedures for operation of the facility;

15.3.b. Maintenance and security of the facility;

15.3.c. Employment, credentialing, evaluation, scheduling, training and management of staff;

15.3.d. Protection of consumer rights;

15.3.e. Conformity of the program with federal confidentiality regulations (42 CFR Part 2);

15.3.f. Security of medication storage and safe handling of medications;

15.3.g. Management of the facility budget;

15.3.h. Implementation of governing body policy; and

15.3.i. Communication with the governing body.

15.4. The administrator shall have at minimum a bachelor's degree in an appropriate area of

study and a minimum of four year's experience in substance abuse or mental health treatment.

15.5. Each program shall have a designated group of individuals to serve in a non-managerial advisory capacity to the administrator and governing body. The advisory council shall consist of individuals served by the program, at least one staff representative and interested community representatives and/or advocates. The advisory council shall not have access to any patient identifying information and the staff liaison to the administrator shall be responsible for ensuring that no identifying information is provided to the council. The advisory council shall meet at least quarterly during hours other than when patients are present in the building and shall:

15.5.a. Review program policies and procedures annually or as proposed for revision;

15.5.b. Review incidents and grievances quarterly;

15.5.c. Review administrative discharges quarterly;

15.5.d. Make recommendations for operational changes or improvements;

15.5.e. Be trained in patient confidentiality regulations;

15.5.f. Keep records of meetings and describe business conducted, members present and members absent; and

15.5.g. The advisory council shall work to assist the program in identifying and addressing/resolving community problems such as traffic, patient loitering and medication diversion so as to ensure the program operations do not adversely affect community life.

§64-90-16. Facility and Clinical Environment.

16.1. Each program shall have:

16.1.a. Sufficient space and adequate equipment for the provision of all services specified in the program's description of treatment services;

16.1.b. Clean, safe and well-maintained patient and staff areas;

16.1.c. A secure room and lockable equipment for patient records;

16.1.d. Private offices or areas for individual and group therapeutic meetings, sufficient in number to address the counseling and treatment needs of the population served;

16.1.e. Sanitary and secure dosing areas;

16.1.f. Sufficient restrooms for the estimated patient population with areas for observation of specimen production, if necessary; and

16.1.g. Adequate parking areas for the expected flow of traffic.

16.2. The program may provide security personnel in lobby and parking areas (either clinic staff or contracted) if the population served or clinic environment warrant such an arrangement. If contracted staff is utilized, they must be trained in patient confidentiality.

§64-90-17. Staffing.

17.1. Medical Director.

17.1.a. Each program shall have a designated medical director who shall be a physician.

17.1.b. Physician authority over the medical aspects of treatment is mandatory. The medical director shall be ultimately responsible for all treatment decisions and for operation of medical aspects of the treatment program.

17.1.c. The medical director is responsible for:

17.1.c.1. Administration and supervision of all medical services; and

17.1.c.2. Ensuring that the program is in conformance with all applicable local, state, and federal regulations regarding the medical treatment of opioid addiction.

17.1.d. The medical director shall be a physician licensed to practice medicine or osteopathy in the state of West Virginia. He or she shall have either:

17.1.d.1. Demonstrated experience in opioid treatment; or

17.1.d.2. A written plan to attain competence in opioid treatment within twelve months. During that time he or she shall be supervised on a regular basis by a physician with demonstrated competence in the field of opioid treatment. Consultation/supervision may be provided by telephone or video conferencing and shall be documented, initialed/verified (either in ink or electronically) and dated by both the supervising physician and the supervised physician. The administrator shall be responsible for maintaining documentation in a file which is current and readily available at all times. The physician's written plan to attain competence shall be submitted to the state authority for approval within two weeks of employment. The state authority may request periodic documentation of continuing education during the initial twelve months and afterward if the documentation provided at the end of that period is not satisfactory. The administrator shall be responsible for ensuring that the plan of development is completed within the approved time lines.

17.1.e. The medical director shall be responsible for maintaining continuing education in the field of addictions on a documented and ongoing basis.

17.1.f. The program may employ and utilize program physicians and physician

extenders such as physician's assistants, nurse practitioners and registered nurses working within their scope of practice. All shall have:

17.1.f.1. One year's experience in opioid treatment settings; or

17.1.f.2. An educational plan for obtaining competence in opioid treatment methods and addictions approved by the medical director who shall certify the individual's completion of the plan when such completion occurs to the satisfaction of the medical director.

17.1.g. Program physicians and physician extenders operating under a plan of education shall be supervised by the medical director at a frequency appropriate for the qualifications and experience of the employee. Educational plans shall be documented and maintained by the program sponsor/administrator, who shall be responsible for ensuring that documentation of completion of the educational plan is present and that the medical director monitors and certifies satisfactory completion of the plan(s). Because the medical director is ultimately responsible for all medical services provided by the program, only the medical director can approve the educational programs and the ability of the program physician and/or physician extender to work independently within his/her scope of practice. The medical director shall provide an affidavit in each staff file indicating that the medical staff person has completed their educational program successfully and is approved to provide services on an independent basis within his or her scope of practice.

17.1.h. Licensed practical nurse shall provide services only under the direction or supervision of a registered nurse or the program physician.

17.2. Counseling Staff.

17.2.a. Each patient of the program shall be assigned a primary counselor who shall have:

17.2.a.1. A bachelor's degree and either licensure/certification or enrollment in the process of licensure as a social worker and/or certification as an addictions counselor;

17.2.a.2. A master's degree and licensure/certification or enrollment in the process of licensure or certification in the individual's chosen field and/or as an addictions counselor; or

17.2.a.3. Certification or enrollment in the process of obtaining certification as an addictions counselor.

17.2.b. Ratios of primary counselor to persons served shall be adequate to allow sessions to occur as mandated and to allow persons served access to their primary counselor if more frequent contact is merited by need or requested by the patient.

17.2.c. Counselors who are not independently certified/licensed shall receive direct supervision by a master's level clinical staff person who is either licensed/certified and/or who

has one year's direct experience in the field of opioid treatment and two years of overall experience in a behavioral health field. Supervision shall be provided in a minimum amount of at least one hour of supervision per twenty hours of direct service provided. Supervision may be group in nature but must consist of case consultation and discussion and/or clinical training rather than administrative oversight. Documentation of supervision shall be the responsibility of the administrator and shall be available for review at all times.

17.2.d. Newly employed counselors without experience in an opioid treatment program and other non-physician clinical staff without experience in an opioid treatment program shall receive initial training lasting at least twenty hours and consisting of, at a minimum, the following:

17.2.d.1. Addictions overview;

17.2.d.2. Opioid treatment and basic pharmacology and dosing;

17.2.d.3. Characteristics of the opioid dependent population;

17.2.d.4. Toxicology screening and observation of sample collection;

17.2.d.5. Program policy and procedure;

17.2.d.6. Confrontation, de-escalation and anger management;

17.2.d.7. Cultural sensitivity as necessary and appropriate;

17.2.d.8. Current strategies for identifying and treating alcohol, cocaine and other drug abuse;

17.2.d.9. Identification of co-occurring mental health or developmental disorders; and

17.2.d.10. Other clinical issues as appropriate for the population served.

17.2.e. The program may document that experienced counselors newly employed from other opioid treatment programs may be exempted from mandatory initial training.

17.2.f. Counselors with less than one year of full time experience in the field of opioid treatment shall accompany an experienced counselor at all times for a minimum of two weeks before seeing persons served without immediate and constant supervision.

17.2.g. The primary counselor shall be responsible for developing and implementing the patient's plan of care, in coordination with the medical staff. The plan of care shall address the social, environmental, psychological and familial issues maintaining the individual's maladaptive patterns of drug consumption and other high risk and/or destructive behaviors. The counselor

shall be responsible for assisting the patient to alter life styles and patterns of behavior in order to improve the individual's ability to function adaptively in his family and community.

17.2.h. The program shall have available counselors qualified to deal with issues such as domestic violence, sexual abuse and anger management.

17.2.i. Policies shall ensure that single sex groups and/or same sex counselors will be available to all patients, as needed and clinically indicated.

§64-90-18. Staff Training and Credentialing.

18.1. Each treatment program shall ensure that:

18.1.a. Doctors, nurses and other licensed/certified professional care providers maintain their current license and comply with the credentialing requirements of their own professions;

18.1.b. All clinical staff receive initial education specific to the pharmacotherapies to be used and tailored to the patient populations to be served;

18.1.c. All clinical staff receive continuing education; and

18.1.d. Detailed job descriptions are developed for credentialed and non-credentialed staff that clearly define the qualifications and competencies needed to provide specific services.

§64-90-19. Risk Management.

19.1. Each treatment program shall:

19.1.a. Obtain voluntary, written, program-specific informed consent to treatment from each patient at admission;

19.1.b. Inform each patient about all treatment procedures, services, and other policies and regulations throughout the course of treatment;

19.1.c. Obtain voluntary, written, informed consent to the prescribed therapy from each patient before dosing begins;

19.1.d. Inform each patient that:

19.1.d.1. The goal of medication therapy is stabilization of functioning;

19.1.d.2. Detoxification from opioids over thirty to one hundred eighty days is a treatment alternative to long-term maintenance;

19.1.d.3. At regular intervals, in full consultation with the patient, the provider will

discuss present level of functioning, course of treatment and future goals; and

19.1.d.4. The patient may choose to withdraw from or be maintained on the medication as he or she desires unless medically contraindicated.

19.2. The program shall inform the patient regarding legal requirements and program policies concerning the report of suspected child abuse and neglect as well as other forms of abuse such as violence against women.

19.3. The program shall inform the patient as to federal confidentiality regulations (42 CFR Part 2) and the Health Insurance Portability and Accountability Act of 1996.

19.4. The program shall:

19.4.a. Promulgate and make available a written description of patient rights and responsibilities;

19.4.b. Follow due process procedures for any involuntary terminations of patients; and

19.4.c. Monitor credentialing of all staff to ensure that they maintain current credentials for performing their assigned job duties.

§64-90-20. Life Safety Issues.

20.1. Each treatment program shall:

20.1.a. Develop procedures to ensure that the correct dose of medication is administered and that appropriate actions are taken if a mistake is made, including a mechanism for reporting unusual incidents to appropriate program staff;

20.1.b. Maintain an up-to-date plan for emergency administration of medications in case the program must be closed temporarily, including how patients will be informed of these emergency arrangements;

20.1.c. Provide twenty-four hour, seven day per week access to designated program staff so that patient emergencies may be addressed and dosage levels verified;

20.1.d. Display in facility offices and waiting areas the names and telephone numbers of individuals or agencies who should be contacted in case of an emergency;

20.1.e. Ensure that there is appropriately trained staff on duty at all times who are trained and proficient in cardiopulmonary resuscitation and management of opiate overdose;

20.1.f. Develop and maintain an up-to-date disaster plan that specifies emergency evacuation procedures, fire drills and maintenance of fire extinguishers; and

20.1.g. Establish policies and procedures that address safety and security issues for patients and staff, including training staff to handle physical or verbal threats, acts of violence, inappropriate behavior, or other escalating and potentially dangerous situations, with emphasis on when security guards or police need to be summoned.

§64-90-21. Continuous Quality Improvement Policies.

21.1. Each treatment program shall:

21.1.a. Provide regular and continuous staff education;

21.1.b. Review and recertify program policies and procedures at least annually in conjunction with the advisory council;

21.1.c. Elicit ongoing input into program policies and procedures by patients in consideration of community concerns;

21.1.d. Develop and implement annual patient satisfaction surveys which shall include a review of patient satisfaction with operating hours and pricing of services;

21.1.e. Adhere to universal infection control precautions promulgated by the Center for Disease Control;

21.1.f. Measure and monitor treatment outcomes and processes including, but not limited to:

21.1.f.1. Reduction or elimination of the use of illicit opioids, illicit drugs and the problematic use of licit drugs;

21.1.f.2. Reduction or elimination of associated criminal activities;

21.1.f.3. Reduction of behaviors contributing to the spread of infectious diseases;

21.1.f.4. Improvement of quality of life by restoration of physical and mental health and functional status including employment as appropriate; and

21.1.g. Outcome measurements and results of patient satisfaction surveys shall be collated annually and reviewed by the governing body and the advisory council and reported to the state authority.

§64-90-22. Diversion Control Plans.

22.1. Each program shall develop a diversion control plan that is reviewed and approved by the governing body, advisory council and the state authority.

22.2. Diversion control plans shall minimize the diversion of methadone or other opioid treatment medications to illicit use. The plan shall include:

22.2.a. Clinical and administrative continuous monitoring of potential for and actual diversion including an investigation, tracking and monitoring system of incidents of diversion; and

22.2.b. Proactive planning and procedures for problem identification, correction and prevention.

§64-90-23. Incident Reporting and Adverse Events.

23.1. The program shall develop policies and procedures for comprehensively documenting, investigating, taking corrective action and tracking instances of adverse events/incidents.

23.2. Adverse events/incidents shall be defined as an event which may involve:

23.2.a. Immediate threat to the care or safety of an individual, either staff or patient;

23.2.b. The possibility of serious operational or personnel problems; or

23.2.c. The potential to undermine public confidence in the treatment program.

23.3. Such events shall include, but are not limited to:

23.3.a. Medication errors;

23.3.b. Patient deaths;

23.3.c. Harm to family members or others from ingesting a patient's medication;

23.3.d. Selling drugs on the premises;

23.3.e. Medication diversion;

23.3.f. Harassment or abuse of patients by staff; and

23.3.g. Violence.

23.4. Adverse events/incidents shall be reviewed on a quarterly basis by the advisory council which may choose to make recommendations to administration and/or the governing body regarding improvements in process to prevent further incidents.

23.5. The program shall assure in the event of an adverse incident that:

23.5.a. The incident is fully documented and appropriately reported to the correct state agencies as necessary;

23.5.b. There is prompt investigation and review of the situation surrounding the event;

23.5.c. Timely and appropriate corrective action is taken; and

23.5.d. Ongoing monitoring of any corrective action takes place until effectiveness of the action is established.

23.6. The program shall report any death involving drug overdose or drug-related complications to the state authority within forty-eight hours of program notification of the mortality.

§64-90-24. Patient Rights.

24.1. The program shall have policies and procedures which guarantee the following rights to patients:

24.1.a. The patient has the right to be informed, both verbally and in writing, of clinic rules and regulations and patient's rights and responsibilities. Rights and responsibilities will be posted prominently and reviewed with the patient at admission, at the end of a stabilization period, at the time of an annual treatment review and if any changes have occurred;

24.1.b.The patient shall receive treatment provided in a fair and impartial manner regardless of race, sex, age and/or sexual orientation;

24.1.c. The program shall provide treatment according to accepted clinical practice;

24.1.d. The patient shall receive medications on a schedule which is most accommodating and least intrusive and disruptive for most patients;

24.1.e. The patient shall have an individual treatment plan and a periodic review of the plan;

24.1.f. The program shall provide an adequate number of competent, qualified and experienced professional staff to implement and supervise the treatment plan;

24.1.g. Patients shall be informed about potential interactions with and adverse reactions to other substances, including those reactions that might result from interactions and adverse reactions to alcohol, other prescribed or over-the-counter pharmacological agents, other medical procedures and food;

24.1.h. Patients will be informed regarding financial aspects of treatment, including the consequences of nonpayment of required fees;

24.1.i. Patients will be given an assessment, acceptance into the program, or, in the case of denial of admission, a full explanation and a referral to another program based upon the results of the initial assessment;

24.1.j. Programs shall protect other patients, staff and the public from a patient who acts out. However, the program shall also attempt to determine the cause of that behavior so that an appropriate referral to an alternative method of care can be made;

24.1.k. Patients shall have the right to confidentiality in accordance with federal regulations (42 CFR Part 2) and the Health Insurance Portability and Accountability Act of 1996;

24.1.l. Patients have the right to be informed of the extent of confidentiality, including the conditions under which information can be released without consent, the use of identifying information for the purposes of program evaluation, billing and statutory requirements for reporting abuse;

24.1.m. Patients have the right to give informed consent prior to being involved in research projects and the right to retain a copy of the informed consent form; and

24.1.n. Patients have the right to full disclosure of information about treatment and medication, including accommodation for those who do not speak English, or who are otherwise unable to read an informed consent form.

24.2. The program shall have patient grievance procedures which shall be displayed in the patient care area. Those procedures shall include the following:

24.2.a. The right of patients to express verbally or in writing their dissatisfaction with or complaints about treatment received;

24.2.b. The right to initiate grievance procedures without fear of reprisal;

24.2.c. The right to be informed of the grievance procedure in a manner which can be understood. The procedures should be published, posted in a conspicuous place and easily available to patients. They should include program rules, consequences of noncompliance, and procedures for filing a complaint or grievance;

24.2.d. The right to receive a decision in writing with the reasoning articulated; and

24.2.e. The right to appeal the decision to the state authority or to any other appropriate state or federal agency.

24.3. Administrative withdrawal shall be used only as a sanction of last resort. It is the responsibility of the program to make every attempt before a patient is discharged to accommodate the patient's desire to be referred to an alternative treatment program as appropriate.

24.4. The patient's methadone dose shall not be changed without the patient's knowledge unless the patient signs a document waiving such consent.

§64-90-25. Recordkeeping.

25.1. All records shall be maintained for a minimum of five years from the time that the documented treatment is provided.

25.2. Patient records are confidential and updated in a timely manner.

25.3. Entries are legible and organized in an effective manner, allowing materials to be easily retrieved.

25.4. Program procedures should ensure security of all records including electronic records, if any.

25.5. Individual records shall contain:

25.5.a. Identifying and basic demographic data and results of the screening process;

25.5.b. Documentation of program compliance with the program's policy regarding prevention of multiple admissions;

25.5.c. Initial assessment report;

25.5.d. Narrative biopsychosocial history completed within thirty days of the patient's admission;

25.5.e. Medical reports including results of physical examination; past and family medical history; review of systems; laboratory reports, including results of required toxicology screens; and progress notes, including documentation of current dose and other dosage data. Information in the medical record is entered by physicians and other licensed health professionals;

25.5.f. Dated case entries of all significant contacts with patients, including a record of each counseling session in chronological order;

25.5.g. Dates and results of case conferences for patients;

25.5.h. The initial treatment plan, any amendments to the plan, reviews of the plan and the long-term treatment plan, including any amendments to that document and reviews thereof;

25.5.i. Documentation that services listed in the plan are available and have been provided/offered;

25.5.j. A written report of the process and factors considered in decisions impacting patient treatment (e.g., take-home medication privileges, changes in counseling sessions, changes in frequency of toxicology screens) or any other significant change in treatment, both positive and negative;

25.5.k. A record of correspondence with patient, family members and other individuals and a record of each referral for services and its results;

25.5.l. Documentation that the patient was provided with a copy of the program's rules and regulations and a copy of the patient's rights and responsibilities and that these items were discussed with her or him;

25.5.m. Consent forms, release(s) of information, prescription documentation, travel, employment and "take-home" documentation, etc.; and

25.5.n. A closing summary, including reasons for discharge and any referral. In the case of death, the cause of death is documented.

§64-90-26. Records of Storage, Dispensing and Administering Medications.

26.1. Each program has policies and procedures consistent with the United States Drug Enforcement Administration's statutes and regulations.

26.2. Each medication order and dosage change is written on an acceptable order sheet signed by the physician.

26.3. Each dosage dispensed, prepared or received is recorded and accounted for by written signed notation in a manner which creates a perpetual and accurate inventory of all methadone in stock at all times.

26.4. Each dose is recorded on an administration sheet at the time that the dose is administered or dispensed and also on the patient's individual medication dose history.

26.5. The person administering or dispensing medications shall be qualified to do so by their scope of practice and shall sign or initial and date each notation.

26.6. If initials are used, the full signature of the qualified person administering or dispensing appears at the end of each page of the medication sheet.

26.7. The substance is totaled in milligrams daily.

26.8. Programs must have a procedure for calibrating medication dispensing instruments consistent with manufacturer's recommendations to ensure accurate patient dosing and substance tracking.

§64-90-27. Staff Files.

27.1. Programs shall maintain individualized personnel files as a record of employment. These files shall contain:

27.1.a. Application for employment;

27.1.b. Date of employment;

27.1.c. Documentation of orientation, internal and external training and continuing education;

27.1.d. Documentation of licensing and/or credentialing;

27.1.e. Documentation of ongoing supervision, as appropriate;

27.1.f. Detailed job descriptions;

27.1.g. Performance evaluations, done at least annually by the employee's immediate supervisor; and

27.1.h. Evidence that the employer has determined that the employee has never been convicted of a felony and/or documentation of a waiver from the state authority allowing the program to employ an individual with a history of a felony conviction.

§64-90-28. Patient Admission Criteria.

28.1. The program physician shall document that treatment is medically necessary.

28.2. Criteria for admission must be consistent with those outlined in the definition of opioid dependence in the Diagnostic and Statistical Manual of Mental Disorders (current edition). The person desiring admission must be over eighteen years of age. Exceptions may be made on extremely rare occasions by application to the state authority.

28.3. All admissions shall include documentation regarding medical necessity and program eligibility for opioid treatment that includes:

28.3.a. Objective evidence of current physical dependence/tolerance to an opioid with documentation of the signs and symptoms of withdrawal;

28.3.b. Onset of opioid physical dependence at least one year prior to admission with continuous use the greater part of the year; and

28.3.c. Multiple and daily self-administration of an opioid.

28.4. In addition to the above admission criteria, the following behavioral signs which support the diagnosis shall be discussed and documented, although none are considered required for admission:

28.4.a. Unsuccessful efforts to control use;

28.4.b. Time spent obtaining drugs or recovering from the effects of abuse;

28.4.c. Continual use despite harmful consequences;

28.4.d. Obtaining opiates illegally;

28.4.e. Inappropriate use of prescribed opiates;

28.4.f. Giving up or reducing important social, occupational or recreational activities;

28.4.g. Continuing use of the opiate despite known adverse consequences to self, family or society; and

28.4.h. One or more unsuccessful attempts at gradual removal of physical dependence on opioids (detoxification) using methadone or other appropriate medications.

28.5. The absence of physiological dependence should not be an exclusion criterion, and admission may be clinically justified. Individuals in some populations may be susceptible to relapse to opioid addiction leading to high-risk behaviors with potentially life threatening consequences. Admission of individuals with no opioid tolerance shall call for small/reduced initial doses of methadone with careful monitoring during the induction phase of treatment.

28.6. Program policies and procedures shall allow for waiving the admission criteria of physical dependence or one-year history of addiction when the person seeking admission meets one of the following criteria:

28.6.a. The person has been released from a penal facility within six months;

28.6.b. The person has been recently released from a chronic care facility and is at risk of relapse;

28.6.c. The person has been previously treated or addicted and is at risk of relapse; and

28.6.d. The person is a pregnant woman.

§64-90-29. Admissions Committee.

29.1. Exceptions to the general admissions criteria must be documented and approved by an admissions committee consisting of the program administrator or his or her designee, the medical

director or his or her designee and a senior counselor. Exceptions shall be monitored and tracked annually for relevant clinical patterns and shall be submitted to the state authority or other monitoring body upon request.

§64-90-30. Multiple Program Enrollments.

30.1. The program shall have a procedure which shall ensure that no patient is enrolled in more than one opioid treatment program.

30.2. The procedure shall take into account requirements for patient confidentiality.

30.3. When practicable, the program shall obtain a release of information from the patient in order to check the records by telephone or fax of every opioid treatment program within one hundred miles of the program site so as to ensure that the patient is not currently enrolled in those programs as well. The release of information shall state that only prior admissions may be the subject of inquiry, not contacts without admission. Results of that check shall be contained in the clinical record. This check shall be duplicated if the patient is discharged and readmitted at any time.

§64-90-31. Initial Assessment/Screening.

31.1. The initial assessment shall focus on the individual's eligibility/need for treatment and shall provide indicators for initial dosage level, should admission be deemed appropriate.

31.2. A comprehensive biopsychosocial assessment shall be completed within thirty days of admission when the patient is stable and able to fully participate.

31.3. The initial assessment shall include:

31.3.a. Brief physical examination;

31.3.b. Immediately relevant health history (e.g., determination of chronic or acute medical conditions such as diabetes, renal disease, hepatitis, sickle cell anemia, tuberculosis, HIV exposure, sexually transmitted disease, chronic cardiopulmonary disease and pregnancy);

31.3.c. Determination of currently prescribed medications;

31.3.d. Evaluation of other substances of abuse;

31.3.e. Determination of current opioid dependence;

31.3.f. Determination of length of addiction;

31.3.g. Toxicology screen to determine immediate use of opiates; and

31.3.h. Full toxicology screen to identify use of other drugs including opiates, methadone, amphetamines, cocaine, barbiturates, benzodiazepines and marijuana.

31.4. Whenever possible and with patient permission, the intake process shall include a non-addicted family member or significant other to assist in provision of accurate information and full understanding and retention of instructions given to the patient.

31.5. Within seven days a more comprehensive medical evaluation shall be completed including:

31.5.a. Comprehensive physical evaluation;

31.5.b. Comprehensive psychiatric evaluation including mental status examination and psychiatric history;

31.5.c. Personal and family medical history;

31.5.d. Comprehensive history of substance abuse, both personal and family;

31.5.e. Tuberculosis skin test and chest x-ray, if skin test is positive;

31.5.f. Screening test for syphilis;

31.5.g. Other tests as necessary or appropriate (e.g., CBC, EKG, chest x-ray, pap smear, hepatitis B surface antigen and hepatitis B antibody, HIV testing);

31.5.h. Repeat full toxicology screen at fourteen days to identify use of other drugs including opiates, methadone, amphetamines, cocaine, barbiturates, benzodiazepines and marijuana; and

31.5.i. Obtain complete medical records from other providers with patient permission.

31.6. Laboratory tests that are not directly conducted by the program may be provided:

31.6.a. By the person's primary care physician;

31.6.b. By other healthcare providers; and

31.6.c. By a medical clinic.

31.7. The program shall be responsible for obtaining and maintaining documentation of required laboratory tests performed by an alternative provider. Alternative providers may not supply toxicology screens unless they meet the required quality guidelines, content and timelines.

31.8. Tests not directly conducted by the program at admission shall have been conducted

within the ninety days prior to admission.

31.9. Within thirty days, the program shall complete a full biopsychosocial evaluation which shall be used to develop the long-term plan of care. The biopsychosocial evaluation shall integrate information obtained in the comprehensive medical evaluation.

31.10. The assessments shall include information obtained from:

31.10.a. The patient;

31.10.b. Family members, when applicable or permitted;

31.10.c. Friends and peers, when appropriate and permitted; and

31.10.d. Other appropriate and permitted collateral sources.

31.11. The psychosocial assessment shall include information about the person's:

31.11.a. Personal strengths;

31.11.b. Individualized needs;

31.11.c. Abilities and/or interests;

31.11.d. Presenting problems including a thorough analysis of the individual's addictive behaviors such as:

31.11.d.1. Licit and illicit drugs used, including alcohol;

31.11.d.2. Amounts used;

31.11.d.3. Frequency of use;

31.11.d.4. Duration of use;

31.11.d.5. Symptoms of physical addiction;

31.11.d.6. History of treatment for addictive behaviors;

31.11.d.7. Adverse consequences of use;

31.11.d.8. Inappropriate use of prescribed substances;

31.11.e. Urgent needs, including suicide risk;

31.11.f. Previous behavioral health services, including:

31.11.f.1. Diagnostic information;

31.11.f.2. Treatment information;

31.11.f.3. Efficacy of current or previously used medication;

31.11.g. Physical health history and current status;

31.11.h. Diagnosis(es);

31.11.i. Mental status;

31.11.j. Current level of functioning;

31.11.k. Pertinent current and historical life situation information, including his or her:

31.11.k.1. Age;

31.11.k.2. Gender;

31.11.k.3. Employment history;

31.11.k.4. Legal involvement;

31.11.k.5. Family history;

31.11.k.6. History of abuse;

31.11.k.7. Relationships, including natural supports;

31.11.l. Use of alcohol and tobacco;

31.11.m. Need for, and availability of, social supports;

31.11.n. Risk-taking behaviors;

31.11.o. Level of educational functioning;

31.11.p. Medications prescribed not a target of treatment or concern;

31.11.q. Medication allergies or adverse reactions to medications;

31.11.r. Adjustment to disabilities/disorders; and

31.11.s. Motivation for treatment.

31.12. The psychosocial assessment shall result in the preparation of a concise interpretive multidisciplinary summary that:

31.12.a. Is based on the assessment data;

31.12.b. Describes and evaluates the level and severity of the individual's addictive behaviors;

31.12.c. Is used in the development of the individual plan of care; and

31.12.d. Identifies any co-occurring disabilities/disorders that should be addressed in the development of the individual plan of care.

§64-90-32. Orientation.

32.1. Each person admitted shall receive program orientation. The orientation shall be made orally at the earliest opportunity that the individual is stable and capable of understanding and retaining the information presented. Information provided in the orientation shall be given to the patient at the time the decision is made to admit the patient, regardless of his or her condition.

32.2. Orientation shall include:

32.2.a. An explanation of:

32.2.a.1. The rights and responsibilities of the patient;

32.2.a.2. Grievance and appeal procedures;

32.2.a.3. Alternative treatments available for treatment of opioid addiction, whether offered by the program or not, and a description of the potential benefit, risks and costs of each. The state authority shall be responsible for providing informational materials to be used in discussing alternative treatments. The patient shall receive a copy of the materials for later review;

32.2.b. An explanation of the program's:

32.2.b.1. Services and activities;

32.2.b.2. Expectations and rules;

32.2.b.3. Hours of operation;

32.2.b.4. Access to after-hour services;

32.2.b.5. Confidentiality policy;

32.2.b.6. Toxicological screening policies;

32.2.c. An explanation of any and all financial obligations, fees, and financial arrangements for services provided by the program;

32.2.d. Familiarization with the premises;

32.2.e. A description of the program's policies regarding:

32.2.e.1. Use of alcohol on or prior to entering the premises;

32.2.e.2. Smoking;

32.2.e.3. Illicit or licit drugs brought into the program;

32.2.e.4. Weapons brought into the program;

32.2.f. Identification of the counselor assigned to the person's case and contact information for that counselor;

32.2.g. A copy of the program rules identifying the following:

32.2.g.1. Any restrictions the program may place on the patient;

32.2.g.2. Events, behaviors, or attitudes that may lead to the loss of rights or privileges for the patient;

32.2.g.3. Means by which the patient may regain rights or privileges that have been restricted;

32.2.h. Identification of the purpose and process of the assessment; and

32.2.i. A description of how the individual plan of care will be developed and the person's participation in it.

32.3. When applicable, an explanation of the program's services and activities include a description of any possible:

32.3.a. Sanctions;

32.3.b. Interventions;

32.3.c. Incentives; and

32.3.d. Administrative discharge criteria.

32.4. Upon admission, the patient shall also receive written documentation of the following information:

32.4.a. Signs and symptoms of overdose and when to seek emergency assistance;

32.4.b. A formal agreement of informed consent to be signed by the patient and a copy retained by him/her;

32.4.c. Patient's rights;

32.4.d. Confidentiality policies; and

32.4.e. Description of processes for dispensing of medication.

32.5. As soon as the individual is stable and capable of understanding, the patient shall receive group or individual education on the following:

32.5.a. Information at admission in Subsection 32.4.;

32.5.b. The nature of addictive disorders including the great likelihood that addiction is a relapsing disease, likely to have grave medical and social consequences if not treated on an ongoing basis;

32.5.c. The anticipated benefits of treatment;

32.5.d. The nature of the recovery process;

32.5.e. HIV spectrum and other infectious diseases;

32.5.f. Potential drug interactions;

32.5.g. Self help groups if any are available;

32.5.h. Medical issues related to detoxification from opioid agonist medication;

32.5.i. The special risk of withdrawal from methadone and detoxification to pregnant women and the fetus (as appropriate);

32.5.j. Characteristics of the medications administered and/or prescribed by the program;

32.5.k. Drug safety issues;

32.5.l. Dispensing procedures; and

32.5.m. Side effects of medications administered or prescribed by the program.

§64-90-33. Initial Plan of Care.

33.1. Within seven days of admission, the program shall have developed an initial plan of care which shall guide the treatment provided to the patient during the first thirty days with the program. The plan shall include:

33.1.a. Completion of program orientation;

33.1.b. Ongoing education regarding addiction, HIV/aids, hepatitis and communicable diseases;

33.1.c. Consistent program attendance, both for dosing and counseling sessions;

33.1.d. Elimination of withdrawal symptoms and opioid craving;

33.1.e. Cessation of illicit drug use; and

33.1.f. Other issues unique to the needs of the individual.

33.2. Patients are frequently in poor physical health and may require other health care. Programs without primary care onsite shall refer patients for appropriate laboratory tests and follow-up on results.

§64-90-34. Admissions.

34.1. The admissions and initial dosing decision shall ultimately rest with the medical director or his or her designated program physician.

34.2. The admissions physical examination may be delegated to an experienced medical professional working within the scope of his or her licensure and directly supervised by the medical director or an approved program physician.

34.3. The admissions assessment shall be conducted by a master's level, experienced professional staff member working within his or her scope of practice or by a bachelor's level practitioner with two years of experience performing psychosocial assessments in behavioral health or one year's experience performing assessments in an opioid treatment program.

34.4. The admission and initial dosing of the patient may take place only after being seen by a program physician, or physician extender who:

34.4.a. Has consulted by telephone or in person with the program physician;

34.4.b. Is approved by the medical director; and

34.4.c. Has completed his or her plan of development.

34.5. The program physician or physician extender shall review the accumulated data directly with the individual and confirm a diagnosis of opioid addiction of sufficient severity to warrant admission. The physician or physician extender and patient shall both sign and date that such review occurred.

34.6. Whenever possible, the patient shall be admitted only after observation by and interview with the program physician. Under unusual circumstances, an approved physician extender may conduct the interview and observation and obtain telephone or fax orders from the physician to initiate treatment; however, the patient admitted under those circumstances must be seen by the physician within three working days of admission for verification of appropriate admission and treatment.

34.7. Exceptions to admission policy shall be reviewed and tracked by the admissions committee and available to regulatory bodies.

§64-90-35. Dosage Principles.

35.1. The dose of methadone or other medications shall be individually determined on the basis of good clinical judgment after review by a physician or other professional practitioner with prescribing privileges for the medication in question.

35.2. Doses shall be sufficient to produce the desired response in the patient for the desired duration of time, with allowance for a margin of effectiveness and safety.

35.3. Dosages shall ultimately:

35.3.a. Prevent the onset of subjective and/or objective signs of opioid abstinence syndrome for twenty-four hours or more;

35.3.b. Reduce or eliminate drug cravings; and

35.3.c. Block the effects of illicitly acquired opioids without inducing persistent euphoric or other undesirable effects.

35.4. The initial full-day dose of medication is based on the physician's evaluation of the history and condition of the patient.

35.5. The usual initial dose of methadone should be from 20 to 30 milligrams. Reasons for exceeding an initial dose of 30 milligrams need to be documented in the clinical chart and should not exceed 40 milligrams unless the physician or prescribing professional documents in the record that 40 milligrams did not suppress opiate abstinence symptoms after a three-hour period

of observation.

35.6. When dispensing opioid agonists, the program shall:

35.6.a. Ensure that the program physician:

35.6.a.1. Orders the medication and/or dosage change; and

35.6.a.2. Signs for the medication and/or dosage change;

35.6.b. Ensure that each dose is recorded:

35.6.b.1. In the individual record of the patient;

35.6.b.2. Using a method to ensure that an accurate inventory of all medication in stock is available.

35.7. The program physician or other approved physician extender shall meet with each patient prior to prescribing the initial dose as described in Subsection 34.6. The program physician or a physician extender shall then meet with the patient as follows:

35.7.a. During the first month, the program physician or physician extender shall meet individually with the patient at least once per week to discuss dosage and symptoms. The weekly meetings shall occur until the dosage is considered stable by the patient and the physician;

35.7.b. Only the program physician may approve changes in dosage or take-home privileges; and

35.7.c. The program physician or approved physician extender shall meet with the patient annually to perform a medical screening and to discuss the possibility of consideration of titration of medications. Such discussion shall be documented along with the individual's decision to continue medications at current levels or to begin a slow titration process.

35.8. The program shall be responsible for proper medication documentation which shall include:

35.8.a. The signature or initials of the qualified person administering medication;

35.8.b. The exact number of milligrams of the substance dispensed; and

35.8.c. The daily totals of the substance dispensed.

35.9. The maintenance dose must be individually determined. There shall be no use of standardized scales or protocols of medication increase/adjustment. Adjustments upward or downward in dosage shall not be made either as punishment or reward but shall be justified by

the clinical documentation of patient condition, subjectively and objectively.

35.10. Dosage adjustment shall be guided by outcomes criteria, which shall be documented and include:

35.10.a. Cessation of withdrawal symptoms;

35.10.b. Cessation of illicit opioid use as documented by:

35.10.b.1. Negative drug tests;

35.10.b.2. Reduction of drug-seeking behavior;

35.10.c. Establishment of a blockade dose of an agonist;

35.10.d. Absence of problematic craving as documented by:

35.10.d.1. Subjective report;

35.10.d.2. Clinical observations; and

35.10.e. Absence of signs and symptoms of too large an agonist dose after an interval adequate for the patient to develop complete tolerance to the blocking dose.

35.11. The program shall have a mechanism through which the patient can discuss dosing with appropriate staff members regularly and upon request. This mechanism shall be clearly described to the patient during orientation/admission and at least annually thereafter. Such description shall be documented and initialed and dated by the patient.

35.12. The ordering physician shall ensure that the justification for daily doses above 100 milligrams is documented in the patient's record.

35.13. The total dose of methadone and the interval between doses may be adjusted for patients documented to have atypical metabolic patterns or those prescribed other concurrent medications which alter rates of methadone metabolism.

35.14. The program shall have the capability of obtaining medication blood levels when clinically indicated.

35.15. The state authority shall be responsible for development of practice guidelines for alternative treatments such as buprenorphine as they become available. The guidelines shall be in conformance with any federal guidelines available. The program shall be responsible for remaining in conformity with practice guidelines as issued by the state authority.

§64-90-36. Admission for Detoxification.

36.1. Programs shall offer detoxification services as an admission alternative. All potential patients shall be offered long-term detoxification as an admission alternative; however, programs may choose to offer short-term detoxification for those patients who desire such a service.

36.2. Short-term detoxification services shall be defined as those projected to last fewer than thirty days. Unsupervised doses of medication may not be permitted to those patients admitted for short-term detoxification except through an exception procedure with the state authority.

36.3. Long-term detoxification services shall be defined as those projected to last more than thirty, up to one hundred eighty or more days, depending on clinical need. Frequency of access to unsupervised-medications shall be determined by the program physician but shall never exceed the frequency allowed to individuals in maintenance treatment. Violations of program policy regarding take-home doses and program compliance shall be considered by the physician and team in a manner consistent with, or more stringently than, violations of policy with regard to maintenance take-homes.

§64-90-37. Counseling.

37.1. Because so many opioid dependent patients also abuse other illicit or prescription substances, counseling is essential to promote and guide the patient to a more productive life style of abstinence from illicit medications/drugs.

37.2. The primary counselor shall be responsible for developing and implementing the patient's plan of care, in coordination with the medical staff. The plan of care shall address the social, environmental, psychological and familial issues maintaining the individual's maladaptive patterns of drug consumption and other high risk and/or destructive behaviors. The counselor shall be responsible for assisting the patient to alter life styles and patterns of behavior in order to improve the individual's ability to function adaptively in his family and community.

37.3. The clinical staff caseload ratio:

37.3.a. Reflects an appropriate clinical mix of sex, race and ethnicity representative of the population served;

37.3.b. Allows the program to provide adequate:

37.3.b.1. Psychosocial assessment;

37.3.b.2. Treatment planning;

37.3.b.3. Individualized counseling;

37.3.c. Allows for regularly scheduled counseling sessions. Counseling sessions shall be defined as face-to-face interactions in a private location between the patient and the primary counselor. Sessions shall be offered:

37.3.c.1. At least weekly during the first ninety days of treatment;

37.3.c.2. At least twice per month during the remainder of the first year of treatment; and

37.3.c.3. At least monthly thereafter.

37.4. Ratios of primary counselor to persons served shall be adequate to allow sessions to occur as described in Subdivision 37.3.c. and to allow persons served access to their primary counselor if more frequent contact is merited by need or requested by the patient.

37.5. Exceptions to frequency of counselor/patient contact shall be clearly justified by program documentation. The program physician and/or prescribing professional evaluating the patient's eligibility for take-home doses shall carefully consider the patient's participation in the counseling sessions as a factor in his/her decision although justified lack of participation (such as for reasons of employment) shall not be held against the patient in the take-home decision.

§64-90-38. Long-Term Plans of Care.

38.1. When the patient reaches thirty days in treatment, his or her plan of care shall be reviewed and revised by the patient and his individual counselor with input as appropriate from medical staff. This review and revision shall be in writing and placed in the case record within thirty-five days of admission.

38.2. Careful discussion shall be held with the patient regarding the patient's continued desire to remain in the program on a maintenance schedule of medication. Alternatives such as medically-supervised withdrawal shall be presented to the patient at the time of the review of the initial plan of care. The patient shall sign and date a statement indicating that he or she wishes to remain within the program in a maintenance format. If he or she wishes to enter medically-supervised withdrawal, the plan of care shall reflect such a choice. If at any time a patient in good standing wishes to re-enter a maintenance program/format, he or she shall do so in consultation with medical staff.

38.3. The revised plan of care shall be developed in conjunction with the patient and shall be individualized to meet his or her needs. It shall include at a minimum:

38.3.a. Regular attendance and participation in the program, both medical and counseling aspects as deemed necessary by the staff and patient;

38.3.b. Identification of "triggers" for misuse of substances;

38.3.c. Development and use of coping strategies for each "trigger";

38.3.d. Development of a detailed relapse prevention plan;

38.3.e. Meaningful follow-up on any identified mental health issues;

38.3.f. Follow-up on medical/physical issues as necessary;

38.3.g. Vocational evaluation, formal or informal, and a plan to achieve financial stability and independence;

38.3.h. Abstinence from use of illicit substances or abuse of prescription substances; and

38.3.i. Other individual or familial issues as relevant and appropriate.

38.4. After the plan is developed and approved by the patient, the patient shall receive a copy.

38.5. The plan of care shall be reviewed by the patient and staff at least each ninety days. Reviews shall be written and detailed. The review shall encompass each of the objectives identified on the plan. At the time of the review, the patient shall again be presented with the option of medically-supervised withdrawal. Continued stay in the program is the right of the patient who remains in good standing as defined in policy by the governing body. At no time should such a patient feel pressured to enter a program of withdrawal over his or her objections. Programs shall make every effort to retain patients in treatment as long as clinically appropriate, medically necessary, and acceptable to the patient.

38.6. Treatment programs shall provide opportunities for family involvement in therapy.

§64-90-39. Counseling and Other Documentation.

39.1. The primary counselor and/or medical staff shall be responsible for documentation of significant contact with each patient, to be filed in the patient record.

39.2. Such documentation shall include a description of:

39.2.a. The reason for/nature of the contact;

39.2.b. The patient's current condition;

39.2.c. Significant events occurring since prior contact;

39.2.d. Assessment of patient status; and

39.2.e. Plan for action or further treatment.

39.3. Each entry shall be completed within twenty-four hours of the contact and shall be clearly dated and initialed or signed by the staff person involved.

§64-90-40. Toxicology Screens.

40.1. Urine drug screening and other adequately tested toxicological procedures shall be used as an aid in monitoring and evaluating a patient's progress in treatment.

40.2. Drug screening procedures shall be individualized and shall include:

40.2.a. At least eight random drug screens per year for each person receiving methadone maintenance services. The program shall test new patients upon admission and at approximately fourteen days of treatment, then monthly through the remainder of the first year;

40.2.b. More frequent collection and analysis of samples during medically-supervised or other types of withdrawal;

40.2.c. Collection of observed specimens on an unannounced basis when using urine as a screening mechanism should the staff believe that such observation is necessary based on individual behavior or need. Collection shall be done in a manner that assures respect for the patient and minimizes the chance of adulterating or substituting another's urine;

40.2.d. Toxicological analysis for drugs of abuse, including, but not limited to:

40.2.d.1. Opiates including oxycodone at common levels of dosing;

40.2.d.2. Methadone and any other medication used by the program as an intervention;

40.2.d.3. Benzodiazepines (including testing procedures that detect diazepam, clonazepam, alprazolam and lorazepam);

40.2.d.4. Cocaine;

40.2.d.5. Methamphetamine/amphetamines; and

40.2.d.6. Other drugs as determined by community standards, regional variation or clinical indication (e.g., carisoprodol, barbiturates).

40.3. Marijuana shall be included in the testing process on a random basis at least three times per year. Positive marijuana screens shall be carefully clinically evaluated and shall in most cases result in reduction in take-home privileges unless other action is deemed appropriate by the medical director/program physician and primary counselor.

40.4. Collection and testing shall be done in a manner that assures a method of confirmation for positive results and documents the chain of custody of the collection.

40.5. When necessary and appropriate, breathalyzers or other testing equipment may be used

to screen for possible alcohol abuse. No individual shall receive a daily dose who has a breathalyzer result which is equal to or greater than .02. The individual may return to the clinic for dosing during the same day if the breathalyzer results reach acceptable limits.

40.6. The results of toxicological testing shall be used to assist clinical staff in making informed-decisions regarding take-home medication privileges; however, clinical decisions about take-homes or discharge shall not be based solely on toxicological test reports but shall be made using all the clinical data available.

40.7. Programs shall document both the results of toxicological tests and the follow-up therapeutic action taken in the patient record.

40.8. Treatment programs shall work carefully with toxicology laboratories to ensure valid, appropriate results of toxicological screens. Workplace testing standards shall not be appropriate for urine testing. Testing shall be done only by laboratories with appropriate federal certification.

40.9. The physician(s) shall receive training in interpretation of "false negative" and "false positive" laboratory results as they relate to physiological issues, differences among laboratories, and factors that impact absorption, metabolism and elimination of opiates.

40.10. The presence of any potentially licit substance such as benzodiazepines, carisoprodol, barbiturates and amphetamines shall be thoroughly evaluated by the program physician. The program shall verify with appropriate releases of information that:

40.10.a. The patient has been prescribed these medications by a licensed physician for a legitimate medical purpose; and

40.10.b. The prescribing physician is aware that the patient is enrolled in an opioid treatment program.

40.11. If the patient refuses release of information to contact his or her physician but can produce prescriptions and/or other evidence of legitimate prescription (such as current medication bottles, fully labeled), the team shall consider the patient's individual situation and the possibility that he or she may be dismissed from the care of his physician should the physician discover that the patient is in medication-assisted treatment. The program physician will make the ultimate decision as to the patient's continuing care in the clinic and the circumstances of that care.

40.12. Absence of methadone or other program-prescribed medications shall be considered evidence of possible medication diversion and evaluated by the physician and interdisciplinary team accordingly.

40.13. As appropriate and necessary, the state authority shall develop guidelines for frequency of toxicological screening for alternative treatment modalities such as buprenorphine.

§64-90-41. Unsupervised Approved Use (Take-Home Medications).

41.1. The program shall have a policy regarding medication schedules which takes into account each patient's best interests as well as the interests of the public at large (e.g., preventing diversion, ensuring safe storage and security of medication, preventing overdoses). Policies shall not create unnecessary barriers for patients continuing in treatment.

41.2. The interdisciplinary team shall make recommendations to the physician regarding take-home medications for each patient. The physician shall make the final decision regarding approval of medications. Decisions shall be reviewed regularly, at least every ninety days, and more frequently if indicated. Reviews shall be documented in the clinical record.

41.3. Programs shall consider the following criteria in determining patient eligibility for "take-home" medications:

41.3.a. Cessation of illicit drug use;

41.3.b. Regularity of program attendance;

41.3.c. Length of time and level of treatment in medication therapy (ability to responsibly self-medicate);

41.3.d. Absence of known recent criminal activity (especially drug dealing);

41.3.e. Absence of serious behavioral problems;

41.3.f. Absence of abuse of drugs including excessive use of alcohol;

41.3.g. Other special needs of the patient, such as split dosing, physical health needs, pain treatment, etc.;

41.3.h. Capacity to safely store "take-home" medication within the patient's home;

41.3.i. Stability of the home environment and social relationships;

41.3.j. Patient's work, school, or other daily-life activity schedule; and

41.3.k. Hardship experienced by the patient in traveling to and from the program.

41.4. The program physician may approve temporary unsupervised take-home medication for documented family or medical emergencies or other exceptional circumstances. Patterns of emergency take-home provision shall be tracked and monitored by the program and available for review by regulatory bodies. Guest dosing at a nearby clinic is preferred whenever possible.

41.5. The program shall have policies and procedures that address the transfer of persons

served from one clinic to another.

41.6. The amount of take-home medication shall be determined by the program physician in consultation with the interdisciplinary team and shall not exceed:

41.6.a. A single dose each week during the first ninety days of treatment except in those weeks in which a holiday falls, causing the program to be closed, in which case, two doses may be permitted. The single dose shall be that provided to supply the patient during the single day per week the clinic may be closed, barring holidays. If the clinic is open seven days per week, no take-home doses shall be permitted during the first thirty days of treatment, then one per week for the remaining sixty days of the first ninety-day period except for holidays during which the clinic is closed. No clinic shall be open less than six days per week on an ongoing basis;

41.6.b. Two doses per week in the next ninety days of treatment;

41.6.c. Three doses per week in the third ninety days of treatment;

41.6.d. A maximum six-day supply of take-home medication in the remaining months of the first year in treatment;

41.6.e. A maximum thirteen-day supply during the second year in treatment;

41.6.f. A maximum one-month supply of take-home medication:

41.6.f.1. After two years of continuous treatment; and

41.6.f.2. With monthly visits made by the patient.

41.7. The state authority may approve exceptional unsupervised-medication dosages on a case-by-case basis with application by the program physician.

41.8. As appropriate and necessary, the state authority shall develop guidelines for take-home (unsupervised) medications for alternative treatments such as buprenorphine. The program shall be responsible for documentation of adherence to the specified guidelines.

§64-90-42. Medication Security.

42.1. The program shall have policies ensuring responsible handling and secure storage of "take-home" medication in child-proof and tamper-resistant containers. Each patient must demonstrate the ability to provide secure storage for take-home medications.

42.2. The program shall inform patients of their rights and responsibilities in writing in ensuring the security of opioid medications.

42.3. The program shall establish a mechanism for monitoring medications to prevent

diversion. Such a policy may include provisions for random call backs of individuals with more than one week of take-home dosage and accompanying random toxicology screens. Frequency of call backs and toxicology screens shall be individually determined by the multidisciplinary team.

§64-90-43. Concurrent Alcohol and Polysubstance Abuse.

43.1. The program shall address abuse of alcohol and other non-opioid substances within the context of the medication-assisted therapy effort.

43.2. Program staff shall be trained and knowledgeable regarding current effective strategies for treating alcohol, cocaine and other drug abuse.

43.3. Ongoing multi-drug use is not necessarily a reason for discharge unless the patient refuses recommended, more intensive levels of care. The multidisciplinary team shall consider the patient's condition and address the situation from a clinical perspective.

43.4. The program shall have a policy regarding treatment of co-morbid disorders such as psychiatric and medical disorders. The goal of such treatment shall be to provide treatment for these disorders in as seamless a fashion as possible, maximizing patient convenience and compliance with appointments and recommendations. Interagency agreements will be developed whenever possible to ensure smooth referral processes and interchange of information.

§64-90-44. Special Populations.

44.1. Mental Health Needs.

44.1.a. Programs shall ensure that patients with mental health needs are identified through the evaluation process and referred to appropriate treatment.

44.1.b. The program shall monitor patients during withdrawal to identify the emergence of symptoms of mental illness.

44.1.c. Programs shall establish linkages with mental health providers in the community.

44.1.d. Programs may provide psychotropic medication management onsite by appropriately trained medical professionals. Plans of care shall describe the goals of psychotropic medication management and shall be reviewed regularly, as specified at Subsection 38.5. Medical documentation shall describe regular contact with the prescribing physician and/or physician extender with appropriate prescription privileges for the distinct purpose of monitoring psychotropic medications prescribed.

44.2. HIV Patients.

44.2.a. The program shall educate all patients regarding HIV/AIDS, testing procedures,

confidentiality, reporting, follow-up care, safer sex, social responsibilities and sharing of intravenous equipment.

44.2.b. Programs shall establish linkages with HIV/AIDS treatment programs in the community.

44.3. Pain Patients.

44.3.a. Patients who are diagnosed with physical dependence and a pain disorder shall not be prohibited from receiving medication-assisted therapy for either maintenance or withdrawal in a program setting, nor shall patients be prohibited from receiving needed pain treatment including, when appropriate, adequate doses of opioid analgesics. Physicians shall receive education in the management of opioid dependence in a context of chronic pain and pain management.

44.4. Criminal Justice.

44.4.a. Programs shall establish agreements and develop procedures to coordinate with agents of the criminal justice system on behalf of patients.

44.5. Pregnant Patients.

44.5.a. Pregnant women seeking and needing treatment shall be enrolled.

44.5.b. The program shall ensure that every pregnant patient has the opportunity for prenatal care, either onsite or by referral. If the arrangement is by referral, the program shall have agreements in place, including informed consent procedures that ensure exchange of pertinent clinical information regarding compliance with the recommended plan of medical care.

44.5.c. If not available elsewhere, the program shall offer a basic instruction on maternal, physical and dietary care as part of its counseling services and document the provision of such services in the clinical record.

44.5.d. With respect to pharmacotherapy for opioid-addicted pregnant women in medication-assisted therapy, the program shall:

44.5.d.1. Maintain patients who become pregnant during treatment on the pre-pregnancy dosage, if effective, and apply the same dosing principles as used with any other non-pregnant patient;

44.5.d.2. Ensure that the initial methadone dose for a newly admitted pregnant patient and the subsequent induction and maintenance dosing strategy reflect the same effective dosing protocols used for all other patients;

44.5.d.3. Monitor the dose carefully, moving rapidly to supply increased or split

dose should such become necessary; and

44.5.d.4. Ensure that if a pregnant patient elects to withdraw from methadone, that withdrawal shall not be initiated by the clinic before fourteen weeks and after thirty-two weeks gestation, that regular fetal assessments are performed as appropriate for fetal age, and that withdrawal is supervised by a physician experienced in addiction medicine.

44.5.e. The treatment program shall ensure appropriate referral for follow-up and primary care for the mother and infant.

44.5.f. If a pregnant patient is discharged, the program will identify the physician to whom the patient is being discharged and this information shall be retained in the clinical record.

44.5.g. The program shall offer onsite parenting education and training to all male and female patients who are parents or shall refer interested patients to appropriate alternative services for such training.

44.5.h. The program shall offer reproductive health education to all patients and appropriate referrals for contraceptive services as necessary.

§64-90-45. Administrative Withdrawal.

45.1. Administrative withdrawal is an involuntary withdrawal/administrative discharge from pharmacotherapy. The schedule of withdrawal may be brief, less than thirty days if necessary.

45.2. Administrative withdrawal may result from:

45.2.a. Non-payment of fees. The program shall make every effort to consider all clinical data including patient participation and compliance with treatment prior to initiating administrative withdrawal for non-payment. If the patient has a history of compliance and cooperation with treatment, the program shall document every effort to explore alternatives to administrative withdrawal with the patient prior to onset of withdrawal. If necessary and unavoidable, the schedule of withdrawal shall be humane;

45.2.b. Disruptive conduct or behavior considered to have an adverse effect on the program, staff or patient population of such gravity as to justify the involuntary withdrawal and discharge of a patient. Such behaviors may include violence, threat of violence, dealing drugs, diversion of pharmacological agents, repeated loitering, and/or flagrant noncompliance resulting in an observable, negative impact on the program, staff and other patients; or

45.2.c. Incarceration or other confinement; however, it is the program's responsibility to work with law enforcement and corrections personnel in order to avoid mandatory withdrawal whenever possible.

45.3. Efforts shall be documented regarding referral or transfer of the patient to a suitable,

alternative treatment program.

§64-90-46. Medical Withdrawal.

46.1. Medical withdrawal occurs as a voluntary and therapeutic withdrawal agreed upon by staff and patient. In some cases the withdrawal may be against the advice of clinical staff (against medical advice).

46.2. The program shall supply a schedule of dose reduction well tolerated by the patient.

46.3. The program shall offer supportive treatment including increased counseling sessions and referral to a self-help group or other counseling provider as appropriate.

46.4. If the patient leaves the program abruptly against medical advice, the program may readmit the patient within thirty days without a formal reassessment procedure. The program shall document attempting to assist the patient in any issues which may have triggered his or her abrupt departure.

46.5. The program shall make provisions for continuing care for each patient following the last dose of medication and for re-entry to maintenance treatment if relapse occurs or if the patient should reconsider withdrawal.

46.6. Female patients shall have a negative pregnancy screen prior to the onset of either administrative or medically-supervised withdrawal.

46.7. For either withdrawal, the program shall have in place a detailed relapse prevention plan developed by the counselor in conjunction with the patient and given to the patient in writing prior to the administration of the final dose.

§64-90-47. Detoxification Programs.

47.1. Detoxification treatment shall mean the dispensing of an opioid agonist treatment medication in decreasing doses to the persons served to alleviate adverse physical or psychological effects incident to withdrawal from the continuous or substantial use of an opioid drug and as a method of bringing the patient to a drug-free state within such period.

47.2. Detoxification is a time-limited, planned withdrawal from medication therapy after a maintenance dose of an opioid agonist is achieved as documented by the program physician. The estimated time of withdrawal shall be specified by the physician and documented; however, can be modified at any time. Such extension shall be briefly documented in the clinical record.

47.3. Detoxification shall be clearly offered as a treatment option at admission to the program and the patient shall sign and date acknowledgment of receipt of such notification.

47.4. When appropriate, the organization shall have cooperative agreements with the

criminal justice system to encourage detoxification services to persons who are:

47.4.a. Incarcerated; or

47.4.b. On probation and/or parole and required to become abstinent.

47.5. The organization shall have procedures for providing detoxification services to persons prior to their incarceration in criminal justice system facilities if possible and foreseeable.

47.6. The program physician, or a physician extender working within the scope of his or her practice and directly supervised by the physician, shall provide onsite medical supervision and oversight of the detoxification program.

47.7. For persons projected to be involved in detoxification for six months or less, the program must offer the patient:

47.7.a. A minimum of two counseling sessions per week for the first month; and

47.7.b. A minimum of two counseling sessions each month thereafter.

47.8. For persons involved in detoxification for fourteen days or less, the program must offer a minimum of four counseling sessions per week.

47.9. Exceptions or refusal to participate shall be documented and tracked by the program.

47.10. The program physician shall determine on an individualized basis the appropriate dosage of opioid agonist medication to ensure stabilization during detoxification. No standardized routines or schedules of increase/decrease of medications may be utilized.

47.11. Urine and/or other toxicological screening instruments shall be used by program staff during detoxification in order to demonstrate the absence of use of alternative licit and/or illicit drugs.

47.12. In detoxification programs of thirty days or less duration, the organization shall have a policy that does not allow more than one unsupervised or take-home medication per week for persons served. If the program operates on a seven day per week basis, no take-home, unsupervised-medications shall be allowed.

47.13. In detoxification programs of more than thirty days duration, the organization shall have a policy that allows the persons served to have the opportunity for take-home medications.

47.14. In detoxification programs of more than thirty days duration, based on the clinical judgment of the program physician, the quantity of unsupervised-medication does not exceed:

47.14.a. One unsupervised dose per week during the first ninety days of treatment

except in a week in which a holiday falls causing the program to be closed. In those weeks, two doses may be allowed; or

47.14.b. Two unsupervised doses per week during the second ninety days of treatment.

47.15. The program shall have a policy regarding detoxification from opioid agonist medication that shall include:

47.15.a. Individualized determination of a schedule of detoxification that is:

47.15.a.1. Well tolerated by the patient;

47.15.a.2. Consistent with sound medical practices;

47.15.b. Implementation of a higher stabilizing dose in the event of impending relapse as appropriate and possible;

47.15.c. Assurances that voluntary detoxification shall be discontinued in the event of relapse and that provisions for maintenance treatment shall be made;

47.15.d. Evaluation and/or testing for pregnancy prior to detoxification; and

47.15.e. Provision for continuing care after the last dose of methadone.

47.16. Counseling services provided in conjunction with detoxification services shall be designed to:

47.16.a. Explore other modalities of care, including drug and alcohol treatment following discharge;

47.16.b. Motivate the patient to continue to receive services or to develop a plan for recovery following discharge; and

47.16.c. Identify triggers for relapse and a coping plan for dealing with each, detailed and in writing and given to the patient prior to discharge. The plan shall be developed in conjunction with the patient.

From: "Raymona Kinneberg" <raymona@bjcinc.com>
To: "Sheila Kelly" <sheilakelly@wvdhhr.org>
Date: 06/20/2005 2:36:07 PM
Subject: OTP regulations

Sheila -

I have a few minor, technical comments on the proposed OTP regulations. Please let me know if I also need to mail them to you in accordance with the comment period notice.

3.29. Physician - An individual licensed in the state of West Virginia by the appropriate licensing board.

If you take this literally, it could mean any person licensed in the state by a licensing board. Shouldn't this definition at least reference to the practice of medicine and/or surgery and perhaps reference the licensing boards for MDs and DOs? For example - an individual licensed to practice medicine and/or surgery under W. Va. Code 30-3 by the Board of Medicine or under 30-14 by the Board of Osteopathic Physicians and Surgeons.

4.3.c. and 4.3.d. These two items are included as sub-items under 4.3., Issuance (of a license), but have to do with waivers and license amendments rather than Issuance. Please consider moving these to their own numbers under section 64-90-4, i.e. 4.4 and 4.5. It appears that placement under Issuance simply occurred when the unnumbered draft received numbers.

15.6 This item is given its own number, under Administrative Organization, but appears more appropriately included under 15.5 related to advisory council. Please consider renumbering it as 15.5.g.

17.1.f. This item still includes licensed practical nurses as a physician extender, but LPNs were specifically deleted as physician extenders under the definition. It appears LPNs should be deleted from this item.

Please let me know if you have any questions.

Raymona

M.D. McNEER
P.O. Box 98
FOREST HILL, WV 24935-0098

June 24, 2005

Sheila Kelly
Program Manager
Behavioral Health Unit
Office of Health Care Facility Licensure and Certification
Capitol and Washington St.
1 Davis Square, Suite 101
Charleston WV 25301

Dear Sheila,

I again thank you and congratulate you on your efforts in drafting the methadone regulations. I think you've done a great job in what I imagine was a difficult and frequently frustrating task. As you know, you can't please all the people all the time, and it sometimes seems you can't please any of the people any of the time.

My final substantive comments and recommendations are the same as they were in my letter to you of September 26, 2004, a copy of which is enclosed for your convenience. *I imagine the page references have changed.* While I stand by *all* my concerns and recommendations, I most emphatically stand by those concerning take-home doses (page 1) and urine drug screens (pages 4 and 5).

I have enclosed a copy of the article we discussed last week concerning carisoprodol abuse.

Please feel free to contact me any time if I can be of any further assistance. I have enjoyed working with you on this project.

Sincerely,

Mike

Michael McNeer M.D.
Enc.

M.D. McNEER, M.D.
P.O. Box 98
FOREST HILL, WV 24935-0098
(304) 466-3000

September 26, 2004

Sheila Kelly
Program Manager
Behavioral Health Unit
Office of Health Facility Licensure and Certification
Room 206
350 Capitol Street
Charleston, WV 25301

Dear Sheila,

I commend and thank you for writing the draft of proposed regulations for OPTs operating in West Virginia. I appreciate that this is just part of the considerable effort you've put forth in this area. I agree with much of the material in this draft, and you have addressed essentially all of my major concerns.

I have included a revision of my primary concerns and recommendations that I previously forwarded to you. I have also enclosed some additional comments on other aspects of your draft. Again, my major concerns center around a few areas:

- Take-home privileges
- Urine drug screening
- Physician qualifications and responsibilities
- Admission criteria
- Dosing stations

Please note that I stand by my current recommendations (dated September 26, 2004) and not those previously forwarded to you. As you will note, some of my recommendations are more restrictive than those previously forwarded to you and some are less so.

I am very happy to see the mandate that those seeking treatment at OTPs are informed of the option of short-term detoxification, long-term detoxification and maintenance treatment.

I have tried to keep my recommendations brief and succinct without much of the commentary in my previous recommendations.

Thank you again for your efforts and for asking me to participate in this process. I am always available if I can be of any assistance to you.

Sincerely,

Michael D. McNeer, M.D.
Enc.
CC: Marshall Long, D.O.
Member, West Virginia House of Delegates, D-Mercer

Larry Kelly, M.D.

I. Take-Home Doses (page 29, #16 of your draft)

I have reconsidered my initial recommendations concerning take-home doses. The following recommendations are for *maximum* take-home doses and require that clinics be open on Sundays.

A. No take-home doses during the first 90 days of treatment.
B. A maximum of one take-home dose between days 91-180 of treatment.
C. A maximum of two take-home doses between days 181 and 270 of treatment.
D. A maximum of four take-home doses during the remainder of the first year of treatment, but no more than two consecutive days of take-home doses.
E. A maximum of 13 take-home doses after successfully completing the first year of treatment with observed ingestion of one dose every 14 days.
F. A maximum of 27 take-home doses after successful completion of two years of treatment of treatment with observed ingestion of one dose every 28 days.
G. Comments and Additions
    1. Clinics should have the *option* of closing on the following major holidays and allowing for one additional take-home dose on those days (including a take-home dose on these holidays for those in the first 90 days of treatment).
        a. New Year's Day (January 1)
        b. President's Day
        c. Martin Luther King Day
        d. Easter Sunday
        e. Labor Day (first Monday in September)
        f. Thanksgiving Day (fourth Thursday in November)
        g. Christmas Day (December 25)
    2. Increases in take-home doses are *absolutely* contingent on maintaining clean urines throughout the previous period and any dirty urine starts that period again. Examples: Any person who has any dirty urine during the first 90 days of treatment should not advance to one take-home dose until all drug screens have been negative for an additional 90 days. The only exception to this rule should be consistently and uniformly positive urines for cannabis during the first 45 days of treatment.
    3. Any dirty urine (with the above exception of cannabis being consistently positive during the first 45 days of treatment) at any time during treatment or long-term detoxification requires that the client revert back to the status of a new admission and starts the privilege of obtaining take-home doses anew.
    4. Rationale on take-home doses and drug screening:
    Forensically collected, tested and confirmed urine drug screening indicates beyond any reasonable doubt illicit drug use and hence continued criminal behavior.
    Further, this above policy should be considered a *regulation* (and not a *clinical decision* based on positive urine results).

II. Physicians (pages 12-14 of your draft)

Since my initial recommendations concerning physician requirements, as you know we have had a meaningful telephone conference with Drs. Payte and McNicholas.

The Federal Regulations regarding physician requirements are quite minimal:

> "All physicians, nurses and other licensed professional care providers, including addiction counselors, must comply with the credentialing requirements of their professions."
>
> *Federal Register, Volume 66, Number 11, page 4096 under "Staff Credentials"*

Likewise, CARF's recommendations (Section 4A, Number 6, page 93) are vague and minimal:

> "The medical director has either:
>
> a. Demonstrated experience in opioid treatment or
> b. Developed a written plan to attain competence in opioid treatment within 12 months (to include Continuing Medical Education in addiction medicine) and be monitored by the designated state authority."

Similarly, the requirements in your draft propose essentially no initial requirements of documented competence in opioid treatment (pages 12-14, numbers 5 and 6).

I have reviewed Pennsylvania's regulations regarding physicians (Commonwealth of Pennsylvania – Department of Health, Chapter 715.6 and Kentucky's regulations (908 KAR 1:340, Section 6) concerning physician's qualifications. You have copies of both Pennsylvania's and Kentucky's regulations.

I have come to realize that my previous recommendations regarding physician qualifications (a stricter adaptation of the Pennsylvania regulations) may preclude qualified physicians from becoming medical directors in OTPs in West Virginia and that it would be extremely difficult, if not impossible, to find physicians with the qualifications outlined in my initial recommendations to work in an OTP in West Virginia.

I recommend that all medical directors at OTPs in West Virginia have at least one year documented competent experience in treating opioid dependence and that all OTPs have a medical director at each facility (e.g., if one organization has six OTPs, each OTP requires a medical director).

The above recommendation would require that you change number 6, page 13, of your draft to read:

> "The medical director shall be a physician licensed to practice medicine or osteopathy in the state of West Virginia. He or she shall have:
>
> a. One year's documented experience in the treatment of opioid dependence in an Opioid Treatment Program
> b. The medical director shall be responsible for maintaining continuing education in the field of addicitons on a documented and on-going basis.
> c. Every OTP facility shall have a medical director with the above qualifications.

III. Admissions Criteria ("Admissions" in your draft)

I have carefully reviewed your section headed "Admissions" (bottom of page 18 through the section headed "Medication Management" at the bottom of page 24). I am in almost total agreement with your draft. I do offer, however, the following clarifications, additions and suggestions.

A. I think it should be made absolutely clear that those persons meeting the physiologic dependence waiver should always start as "new patients" regarding take-home privileges, urine drug screening procedures and other requirements for new admissions.

B. I thing short-term detoxification should be defined as not exceeding 30 days from admission (not 30 days from achieving a stabilizing dose of an opioid agonist) and that long-term detoxification be defined as no more than 180 days from admission (not 180 days after maintenance levels of opioid agonists are attained).

Rationale and note: Obtaining a stabilizing dose of opioid agonist could extend these programs indefinitely. See CARF, Section 4D, #17, 18 & 19, pages 111 and 112.

Also, consistent with my recommendations for no take-home doses during the first 90 days of treatment and no more than one take-home dose during the second 90 days, I think this policy should apply to those in short- and long-term detoxification. (This recommendation is more strict than that recommended by CARF, Section 4D, #19, page 112.

C. 1. Under page 21, #7 of your draft, I am in complete agreement with your recommendations that the initial psychosocial assessment be conducted by a "master's level, experienced professional staff member within his/her scope of practice."

2. Also, under page 21, #7, I agree the "admission and initial dosing of the consumer may take place only after a program physician has reviewed the accumulated data directly with the individual and confirmed a diagnosis of opioid addiction of sufficient severity to warrant admission. The physician and patient should both sign and date that such a review occurred." However, I recommend that the program physician and consumer *always* have a *face-to-face* meeting before the admission and initial dosing take place. *Always. No exceptions.*

IV. Urine Drug Screens (pages 9-10 of your draft)

A. I recommend that all urine drug screens in OTPs in West Virginia include testing for:

1. Methadone (or buprenorphine, if that drug is used)
2. Opioids – both naturally occurring and semi-synthetic – including morphine (heroin is detected by morphine testing also), codeine, oxycodone, hydrocodone, hydromorphone. NOTE: Most drug screens do test for these opioids, but many, until recently, have not been sufficiently sensitive to pick up oxycodone, the active ingredient in OxyContin. I recommend that any drug screen be sensitive to detect oxycodone at common levels of dosing.
3. Cocaine
4. Barbiturates
5. Benzodiazepenes (including testing procedures that pick up diazepam [or metabolites], clonazepam, alprazolam and lorazepam. Some urine drug screens do not pick up some of these most frequently abused benzodiazepenes.)
6. Amphetamines/methamphetamines
7. Cannabanoids
8. Meprobamate (the active metabolite of carisoprodol [Soma] – a particularly commonly abused drug in West Virginia and central Appalachia, usually abused in conjunction with opioid abuse to enhance the high with opioids.

B. I recommend that urine drug screens be done on admission and randomly at least weekly during the first 90 days of treatment, at least bi-weekly during the second 90 days of treatment and at least monthly thereafter. (At an absolute bare minimum, weekly urine drug screens during the first 30 days of treatment, bi-weekly during the remaining initial 180 days and monthly thereafter is acceptable.)

C. Collection and testing

I recommend collection be done in a manner that assures respect for the client and minimizes the chance of adulterating or substituting anothe's urine. Only rarely should observed specimen collection be necessary. Collection and testing should be done in a manner that assures a method of confirmation for positive results and documents the chain of custody of the collection. Testing should be done only by labs with appropriate Federal certification. An official register of federally certified drug testing laboratories is compiled by the Department of Health and Human Services and is published in the Federal Register.

D. Positive tests for licit drugs that may be illicitly used:

Prescription opioid addiction is the leading reason patients in Appalachia seek admission to opioid maintenance programs. Benzodiazepines and carisoprodol are also frequently abused by these patients.

I recommend that the presence of any licit substance (benzodiazepines, carisoprodol, licit opioids, barbiturates and amphetamines) be thoroughly and immediately evaluated by the program physician with absolute verification that the patient has been prescribed any of these drugs by a physician for a legitimate medical purpose and that the prescribing physician is aware that the patient is involved in an opioid treatment program. If such information is not validated (with the appropriate consents from the patient) I think the presence of these otherwise licit substance(s) in the urine be treated as continued illicit drug use regarding progression in take-home doses and frequency of urine drug testing. If the patient does not consent to the above recommended exchange of information, I think he/she should be strongly considered for administrative detoxification and discharge from the program.

E. Rationale for testing for barbiturates:

Although short-acting barbiturates are now no longer widely prescribed or abused, butalbital (e.g. Fiornal) is still commonly prescribed and abused, frequently in conjunction with opioid abuse and dependence.

F. Rationale for meprobamate testing:

Carisoprodol (Soma) is metabolized into meprobamate, a controlled barbiturate-like drug and is detected in the urine as meprobamate. Carisoprodol is a widely abused drug in West Virginia and central Appalachia, particularly in combination with prescription opioids, specifically hydrocodone and oxycodone. Though not controlled by the DEA, it is controlled in West Virginia as a Schedule IV drug. Carisoprodol frequently contributes to multiple-drug overdoses and rarely can be fatal in overdose alone. I emphasize that carisoprodol is a widely abused drug in West Virginia and that its abuse potential and widespread abuse is not generally recognized by the medical profession.

G. Testing for substances not listed above

If there is evidence of abuse of drugs other than those listed above (e.g., Fentanyl) I recommend that it be thoroughly evaluated and tested for if and as indicated.

H. Absence of methadone in urine drug screens

The absence of methadone in urine drugs screens should be considered strong evidence of methadone diversion and so evaluated.

V. Medication Units

The Federal Regulations define a medication unit as "a facility established as a part of, but geographically separate from, an OTP from which licensed private practitioners or community pharmacists dispense or administer an opioid agonist treatment medication or collect samples for drug testing analysis."

Pennsylvania prohibits these units (Chapter 17.25: Standards for Approval of Narcotic Treatment Programs).

Kentucky refers to these units as "medication stations," and places limitations on them (Section 18 of Kentucky Regulations).

I recommend that West Virginia prohibit "medication units" or "dosing stations."

VI. Additional Comments on Your Draft

A. On page 3, your draft states:

"Each licensed program is inspected annually except in those years in which the federally mandated accreditation survey takes place. The program shall submit a copy of the results of the accreditation survey to the Office of Health Facility Licensure and Certification and to the State Authority for that year in lieu of a state licensure inspection."

I do not think the clinics should be exempt from state inspection those years. The Federal Guidelines are much less strict than the proposed state regulations.

B. On page 9, under "Toxicological analysis for drug abuse, including but not limited to," please refer to my recommendations concerning urine drug screens.

C. At the top of page 10, your draft states:

"All toxicological screens shall include testing for opiates and methadone or any other medication utilized by the program as an intervention; however, the program may choose to screen for other required elements on an individually determined random or as needed basis but at no point less than eight times per year." *I think this recommendation is totally insufficient.*

Please refer to my recommendations on urine drug screening. Also, this statement is contradictory to the 11 urine drug screens recommended in another section of your draft.

D. The third paragraph on page 10 reads:

"Procedures to ensure that drug screening results are not used:
a) As the sole basis for treatment decisions.
b) As the sole basis for termination from treatment."

Please recall that I have made it clear that my recommendations requiring advancement in take-home doses and decreasing frequency of urine drug screens as treatment progresses are recommended as a *regulation*, and is therefore not a *clinical decision.*

E. Pages 11 and 12 recommend guidelines for counseling. I am generally okay with your recommendations except

1. I think counseling sessions should have a recommended *minimum* duration of 20 to 30 minutes.
2. I think *all* counselors should have at least a Bachelor's Degree in addition to the other qualifications you have outlined.

F. On pages 12 and 13, you set forth suggested requirements for medical directors and program physicians. Please refer to my recommendations on this matter.

G. On page 16, immediately above "Initial Assessment," there is a bullet without words. Should there be something there, or is this just a typo?

H. From the title at the bottom of page 18 (Admissions) to the section on medication management about two-thirds down page 24, you address recommended policy on admissions. I have addressed all my major recommendations in Section III of my recommendations.

I do suggest

1. that the last sentence under number 4 on page 20 read:

   The medical examination includes at a minimum the following laboratory and testing procedures:

   a. A urine drug screen
   b. A TB skin test or chest X-ray, if the skin test was ever previously positive
   c. A screening test for syphilis

2. On page 21, number 7, I recommend that the paragraph beginning "In rare circumstances ..." be stricken. Please see my recommendations requiring, without exception, a face-to-face meeting between a physician and the new patient before any opioid drug is administered.

I. From the botton of page 24 to the bottom third of page 29, you address the issue of medication management. I offer the following suggestions.

1. On page 25, the second number 3, I recommend striking " ... except in unusual circumstances." As previously noted, I have made it clear that I recommend no exceptions to the suggested requirement that no patient be dosed prior to a face-to-face meeting with a physician.
2. On page 26, I recommend sections 6b and c with the following statement directly from the Federal Guidelines, page 4098:

   "For each new patient enrolled in a program, the initial dose of methadone shall not exceed 30 milligrams and the total dose for the first day shall not exceed 40 milligrams, unless the program physician documents in the patient's record that 40 milligrams did not suppress opiate abstinence symptoms."

J. Under number 13 on page 28, please note my recommendations regarding take-home doses being contingent on clean urine drug screens. As you know, as a matter of regulation, I recommend clean drug screens as outlined in my recommendations under Section I of my recommendations.

K. Please note in this section you have two number 3s and two number 9s that require some editing.

L. On page 29, number 14, you mention "hardships." "Hardships" have been abused by patients to attain additional take-home doses. I recommend all hardships be thoroughly documented and closely monitored by the medical director and entire treatment team.

M. On page 29, number 16, you have outlined your recommendation concerning take-home doses. I totally stand by my recommendations concerning take-home doses in Section I of my recommendations.

N. From the bottom third of page 29 throught the upper third of page 31 you make recommendations concerning medical withdrawal. I am in substantial agreement with these recommendations.

O. You outline your recommendations for detoxification programs beginning on the upper third of page 31. I am in substantial agreement with this section on detoxification except that I recommend

1. That short-term detoxification shall last no longer than 30 days from admission (not "after a maintenance dose of an opioid agonist is achieved as documented by the program physician") and that long-term detoxification not exceed 180 days from admission (not "after a maintenance dose of an opioid agonist is achieved as documented by the program physician").

2. On page 32, near the middle of the page, with the paragraph beginning "Urine and/or other toxicological screening instruments ...," I recommend that these be consistent with my recommendations concerning urine drug screening as opposed to your recommendations concerning "Medication Management."

3. On page 32, with the paragraph beginning "In detoxification programs of 30 days or less duration, ...," I recommend that no take-home doses be given, as I have stated elsewhere.

4. On page 32, with the paragraph beginning "In detoxification programs of more than 30 days' durations, ...," I recommend that no take-home doses be given during the first 90 days of treatment, and that a maximum of one take-home dose be given during the second 90 days of treatment.

P. From the title "Treatment/Service planning" through the end of your draft on page 35, you make recommendations concerning treatment/service planning. I have no substantive disagreement with these recommendations so long as they are internally consistent with other regulations.

From: Ellen Valli <ellenvalli@yahoo.com>
To: Sheila Kelly <sheilakelly@wvdhhr.org>
Date: 07/06/2005 2:42:52 PM
Subject: Re: Fwd: Re: WVa OTP Regulations

Shelia,

There are additional regulations that seem very cumbersome. In point, requiring an advisory committee when we already have in place an executive committee comprising of clinical directors of 5 other programs that meet monthly. We review all the issues you have stated. Two client surveys, and stake holder surveys are completed each year and a client grievance process that is taken very seriously. We document CQI meetings, executive staff meetings, governance and managment meetings, clinical team meetings and all incidents reports.

We are organizing and have sent preliminary invitations to over 50 community organizations and lawyers to come to an open house in September.

Is there any way this could surfice for the advisory commitee you are requesting.

I am also requesting an exception for myself. I hold a CCDC from the State of Maryland and a CCAC from the state of West Virginia. I also have an AA in Human Services and over 14 years in the field of chemical dependency.

I look forward to the challenges that lie ahead in the next year and will be seeking your guidance in clarification of standards.
Take good care,
Ellen

From: Ellen Valli <ellenvalli@yahoo.com>
To: Sheila Kelly <sheilakelly@wvdhhr.org>
Date: 07/06/2005 2:29:45 PM
Subject: Re: Fwd: Re: WVa OTP Regulations

34.3- Suggesting that after orientation of clinical personnel is completed all staff should be adequately prepared to complete a psy-social with their clients. Psyc-socials will be reviewed by clinical supervisor.

Sheila, with increased clinical supervision mandated, it
puts are most experienced staff doing lengthy intake tasks. In addition, how would new staff ever be able to gain the experience needed to preform assessments.

27.1 Documentation of clinical staff is kept by clicical supervisor and avalable for inspection by governing body upon request.

Personel files are not avalable to are spervisors. This wuld make said documentation almost impossible.

From: "Dann White - WVMAP" <wvmap@charter.net>
To: <sheilakelly@wvdhhr.org>
Date: 07/11/2005 1:09:35 AM
Subject: THIS DOCUMENT WAS NOT PICKED UP FOR DELIVERY- PLEASE READ ASAP

Apartment B
1212 Quarrier Street
Charleston Wv 25301-1832
Daniel B. White / project coordinator

Sheila E. Kelly
OHFLAC
Bureau for Public Health
1 Davis Square, Suite 101
Charleston, Wv 25301
RE: DHHR, title 64, WVC 16-1-4 & 27-9-1
Regulation of Opioid Treatment Programs

Ms Kelly,

I apologize for the late hour for delivery of our comments on the OTP Regulations, but I am suffering from physical ailment and infirmity which prevents me from delivering this letter to the Post Office myself. Having no paid assistants to delegate this responsibility to; I was forced to enlist the aid of a family member who will be unable to pick this up from my residence until after 5PM on July 8, 2005. I will send it for an early delivery in hopes that you will include our member's wishes in the record of public comment despite the late arrival. You will find our comments brief.

Our organization; the West Virginia Methadone Advocacy Project, the only group who represents only the interests of Opiate Treatment Program Patients in the state of West Virginia, is the state chapter of The National Alliance of Methadone Advocates, and as such, has followed the progress of these regulations from the first legislative movement to enact such rules, through their passage on the closing days of the 2004 legislature, disguised as a minor property crimes bill, and later through the many different proposed drafts.

We at NAMA and WVMAP can't help but be amazed at the extent your office went to cater to the demands of the critics of OTP in West Virginia Government who started this great effort of rewriting the forty-plus years of Opiate Agonist Treatment experience that culminated in the adoption of C.F.R. 42, part 8, by a group of bureaucrats with virtually no experience with OTPs. Until the national OTP community began to dismay at the folly of such an undertaking; West Virginia's main claim-to-fame in the OTP world was its thirty-plus years of denial when it came to Methadone Maintenance Treatment.

Your further inclusion of one Doctor Michael McNeer of Mercer County; an outspoken competitor and critic of OTP, lacking any personal experience in the field, to a position of being your primary source of information, apparently medical and otherwise, on the topic, will be a source of amazement for people in the know for some time to come. Another shocking report was that you have relied heavily on the employees of local clinic operators for expertise when not one experienced employee was brought into this state to operate a facility, while many of these employees are fine people with a desire to provide quality care, they are hardly in a position, even today, of knowing what if anything was needed in the way of regulation; they are still struggling in many cases to organize the simplest parts of their operations.

Since the drafting process began I have placed a number of critiques from people who are known and respected around the world for their expertise in the field at your disposal. Most notably you heard from Joycelin Woods MA, President of The National Alliance of Methadone Advocates, a person whose efforts contributed greatly to the adoption of the current federal regulations,1 and Doctor Robert Newman MD, MPH, Professor of Epidemiology and Population Health and Professor of Psychiatry at the Albert Einstein College of Medicine in New York, Doctor Newman is also a former White House Advisor on OTP and director of one of the largest OTP facilities in the world.2 To my knowledge your office took no advantage of their expertise or note of even the very least of their suggestions for you.

I have on several occasions raised the concern over how your proposals stripped the most basic of patient rights away from OTP Patients by deleting the right to a patient's representation by a Patient Advocate in all manners of administrative action and matters of redress of grievances by patients. Such a right has long been acknowledged as fundamental in virtually all statements of Patient Rights in the Mental Health and Addiction treatment Fields. All across the state of West Virginia advocates are deployed to see that patient rights are not usurped by the unscrupulous or untrained or lost in favor of staff convenience or operator's profit margins. OTP patients in West Virginia, who down to the very least of which are fully self-funded, operating in a climate of potentially high profit margins, deserve this same protection. What changes you make in respect to this point may be the most telling of all about the validity of your work on these regulations.

I asked several times for a list of persons serving on the committee (?) to draft this document, it was never made available to me, and when I asked to be included in the process myself; volunteering to work as long and hard as would be necessary and citing my many years of involvement in addiction treatment and specifically Methadone Maintenance Treatment (MMT), I was only asked in for a question and answer session with yourself and Merritt Moore in attendance. While I enjoyed the session, you failed to fully avail yourselves of the catalogue of information, facts, and figures on OTP that was in my possession or at my disposal. Perhaps in part due to your failure to involve recovering persons in your work, your final draft shows a real lack of patient perspective on OTP and an unfortunate implication that patients are just the consumers of OTP; when in fact the addict patient themselves are the greatest potential factor in the equation of true recovery from opiate dependence and addiction.

Another area of concern is your attempt to over-elevate the position of patient counselor by specifying a requirement of a four-year degree for those hired to that position. It would seem that if college degrees were in question and the position of counselor was to be raised to the level of a clinician's role of some kind, in today's world a Master's Degree would be the minimum recognized. Since this is typically a paraprofessional, low-paying position, and mostly one of helping patients to negotiate conformance with treatment standards, i.e. collecting lab specimens, assigning clinic days, and keeping current paperwork signed and charted, work typically done by Treatment Technicians and not therapists in the inpatient setting; you have deprived the system of the best source of OTP Counselors there is; the successful and motivated patients who learn the job through their experience in treatment. In most locales this is a long-standing tradition, through their empathy and ability to communicate with other addicts, the recovering person's talents far outstrips the ability of any non-addict, regardless of schooling, to provide quality care, especially those available at this level of pay and benefits.

Another confusing area of these proposals is in the section regarding the diversion of methadone from clinics to the street. These regulations insist that each program have a "diversion control plan" of their own, "reviewed and approved by their governing body, advisory committee, and the state authority". An effective "diversion control plan", if one exists; should be outlined in this document and used by all of the treatment programs subject to these regulations.

At the Federal Level the Substance Abuse and Mental Health Services Administration is charged with the regulation of medically assisted treatment programs. The Drug Enforcement Agency is charged with enforcing the Uniform Controlled Substances Act; including the proper storage, prescribing, and dispensing of methadone and other scheduled drugs. Other than taking care to qualify those patients to whom they extend take-home privileges, occasionally checking to see that those take-home doses are properly stored and used by the patient only, and preventing the sale of medication on their premises, there is little that programs can do to stop such sales

While individual programs certainly are the best starting point in an effort to halt the diversion of clinic methadone; their most effective offering is the ability to educate patients about their responsibility in the take-home process. Programs are not equipped to deal with the "investigation" of diversion incidents, and they certainly have no police powers, therefore they need not be prodded by regulation into stepping over the wide gulf that rightly exists between treatment program and law enforcement agency. There is a great chance that if patients were aware that suspected diversion would be turned over to law enforcement for investigation, such incidents of diversion might be greatly reduced.

The difference in the number of allowed take-home doses in these regulations and those previously allowed in the Federal Regulations are negligible, and do not dramatically affect most patients; thus we

can't help but wonder why any change in these standards at all was necessary. Were such changes made just to satisfy the notion that West Virginia was making their own regulations, to quiet an eager politician, or to simply show some effort on the author's part.

The Federal guidelines, like these, do not automatically grant take-home doses to persons just because they have reached some chronological benchmark like ninety- days, six-months, or one-year on the program. They should be granted based on the needs of individual patients, providing they meet these and other criteria that are more or less standard in the field. Quiet often however, there are cases where a patient's work life and continued employment are threatened by their need to attend treatment during restrictive clinic hours. The useless tightening of time on treatment requirements can only create an atmosphere of hesitance on the part of medical directors to approve requests when such needs arise. We are unaware of any circumstance that would have inspired you to tamper with these guidelines that again were created based on the many years of OTP experience that exists in our nation, was this just done because you could?

One of the most appalling problems in this document is the obvious double standard between patients who are being withdrawn voluntarily from treatment and those who are being administratively discharged. In the case of voluntary detoxification you clearly state that "a program will supply a schedule of dose reduction that is well tolerated by the patient". In the matter of Administrative Discharge, including discharge for the non-payment of fees, your new rules state: "Administrative withdrawal is an involuntary withdrawal/administrative discharge from Pharmacotherapy. The schedule of withdrawal may be brief, less than thirty days if necessary". The suffering of a patient in severe or even moderately severe opiate withdrawals is a horrible experience. The idea that a person who is unable to pay clinic fees any longer should have to suffer these pangs, while the patient who has money to pay is afforded a "well tolerated" dosage reduction seems to fly in the face of professional ethics and, even more importantly, the values of human decency that West Virginians cherish. This cannot continue.

There is so much excess language involved in this document, due to the attempts to micro-manage every transaction between patient and facility, doctor and patient, counselor and patient, and so on. Sections 28 to 32 needlessly try to break the admissions, orientation and treatment process down to its molecular level. This is presumptuous and flies in the face of good sound medical practice, and will prove about as useful as a wet blanket when used in an effort to combat a condition as individual to the sufferer as addiction. Successful addiction treatment is dependent upon creative energy on the part of all involved. Your attempts to tell providers what to think about when looking at their next patient and all that follow, will serve to stifle the treatment process, bog workers down in reams of paperwork, and drive up the already high costs of OTP in our state.

While it seems that we in West Virginia have been fortunate to this point, attracting program operators who have held to ethical treatment since their arrival here. It is unlikely that a non-profit organization would have been persistent enough to break down the old glass walls that kept OTP out of West Virginia from 1971 until 2001, and that addicts who have been able to afford the costs of treatment to date have benefited greatly from it. Despite these facts, it simply makes good sense for our regulators to try and encourage the formation of not-for-profit clinic operations, operations that will pursue Medicaid reimbursements, mobile clinic operations, and in short; all manner and types of OTP programs offering Methadone and Buprenorphine Treatment Protocols to those in need. These regulations are several steps in the wrong direction for these most important milestones in our state's OTP development. A number of operators expressed to me at the AATOD Conference their interest in locating in our state, but changed their mind after reviewing the regulatory climate here. A free and open marketplace is the best hope of patients seeking the best value for quality care. A variety of options in the way of OTP will serve the greatest number of patients.

The requirement that facilities provide a plan for the alternative dispensing of medication in the event of emergent problems with weather, natural disaster, road closure, or other reasons patients and/or staff are unable to reach the program facility. The missing of medication by patients is an intolerable condition that must be avoided with a well-considered emergency plan.
Such a plan would include:
1. A pre-arrangement with a facility where temporary dosing can take place.
2. A source pharmacy where adequate emergency supplies of medication are readily available on short

notice in the event that regular stocks cannot be accessed.
3. A Master List of contact information for patients should be kept in the homes of multiple management employees so that patients can be notified of impending problems, the need to report for emergency advance pick-up of medication, and/or alternate dosing sites and times.
4. A 24 hour emergency number for the facility that is always answered and able to provide emergency information to Doctors, Hospitals, and others in need of emergency medical data on facility patients.
A sign in the Charleston Treatment Center facility advises patients that if conditions are such that they cannot reach their facility to receive their medications, they should report to the parent company's facility in Huntington, West Virginia. This is ludicrous; expecting patients unable to negotiate a trip to a suburban location to be able to make a sixty mile trip to another city to find another clinic. If this state of affairs is allowed to continue, in the not-too-distant future there will be an occasion where a substantial group of patients are unable to dose because of tunnel vision and a lack of planning.

I need to touch on one area at least once more in closing. Every OTP patient in this state is self-supporting in their efforts to recover, and therefore deserve the highest consideration for showing their commitment to recovery. Their desire to change their lives has created a windfall for the providers of that care, and we at WVMAP believe that these providers have been good corporate citizens of our state. In such an environment we have an opportunity to set ambitious standards for future care as we direct our efforts toward making this treatment available to all West Virginians who need it.
Redundant Regulations that duplicate the Regulations of the Federal Government and accreditation agencies are wasteful of state resources and a major bureaucratic and administrative burden on treatment providers; driving up treatment costs and wasting staff energies better directed at patient contact and care. These regulations fall squarely into this category and along with the drain on resources, they embarrass the Department of Health and Human Resources and the State of West Virginia.

We urge that these regulations be held in abeyance until a panel of experienced professionals, patient representatives and advocates, representatives of provider groups draft a set of far less copious guidelines, with an eye toward streamlining the OTP System in West Virginia, deleting regulations that duplicate the guidelines of the Federal Government or independent accrediting agencies, and condense any needed regulations down to a set of concise and simple local regulations that adapts quality OTP practices to the Mountain State.

You will find that on a second effort with the proper input, the arrival at the needed regulations will be a far simpler undertaking, and the result one to be proud of,

Sincerely,

Dann White
WVMAP Project Coordinator
Enclosure/cc: NAMA, Secretary Walker, Governor Manchin, CSAT,

CC: <wvdhhrsecretary@wvdhhr.org>, "Robert Wise" <governor@wvgov.org>, <merrittmoore@wvdhhr.org>