

Title 69 Series 12

Department of Health and Human Resources

Office of Inspector General

Office of Health Facilities Licensure and Certification

MEDICATION-ASSISTED TREATMENT – OFFICE-BASED MEDICATION-ASSISTED TREATMENT

Summary of Public Comments:

Section 1 – General

Comment

1.1 Licensure and Regulation of OMB. Comprehensive Behavioral health Centers (CBHCs) are already licensed by OHFLAC. MAT in a CBHC is but one of many treatment alternatives utilized. Many of the MAT draft rules are not consistent with OHFLAC's behavioral health center licensure rules and also are not congruous with BMS' MAT program requirements. It would be impossible for a CBHC to be compliant with these proposed rules while maintaining compliance with the best practice standards adopted by BMS and OHFLAC's behavioral health licensure rules. Exempt Licensed BHCs from further licensure.

Response

The Department has reviewed this comment, and no changes were made in response. All medication assisted treatment programs and providers are governed by W.Va. Code 16-5Y-1, *et seq.* and therefore governed by 69 CSR 12.

Section 2 - Definitions

Comment

Medication Assisted Treatment is not defined.

Response

The Department has reviewed this comment, and no changes were made in response. Medication Assisted Treatment is defined in W.Va. Code § 16-5Y-2 and incorporated by reference in 64 CSR 12.

Comment

OBMAT is not defined.

Response

The Department has reviewed this comment, and no changes were made in response. Office Based Medication Assisted Treatment is defined in W.Va. Code § 16-5Y-2 and incorporated by reference into 64 CSR 12.

Comment

"Medication-assisted treatment medication" means any medication that is approved by the United States Food and Drug Administration under section 505 of the Federal Food, Drug and Cosmetic Act, 21 U. S. C. § 355, for use in the treatment of substance use disorders that is an opioid agonist and is listed on the schedule of controlled substances in article two, chapter sixty-a of this code. (During legislative consideration of this issue the drugs naltrexone and naloxone were excluded from SB 454. Both of these drugs are used for the treatment of opioid addiction but neither contains an opioid and consequently they are not listed on the schedule of controlled drugs. Absent this definition being inserted in the proposed rule we believe the rule could be interpreted by future regulators to include programs which utilize naltrexone and/or naloxone. The proposed rule is addressing medications used in long-term treatment that contain the active ingredient buprenorphine. Including this definition assures legislative intent is followed.)

Response

The Department has reviewed this comment, and no changes were made in response. Medication Assisted Treatment Medication is defined in W.Va. Code § 16-5Y-2 and incorporated by reference into 64 CSR 12.

Comment

2.3. Advanced Practice Registered Nurse -- Why do you include the definition for Advanced-Practice Nurses but not for Physician Assistants?

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

2.5. Approved Authorities - This regulation does not mention SAMHSA. That group is probably the most important for our programs. While probably not a group used to provide "approval" for state-run programs, it remains (or should be) a center for how to focus treatment programs.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

2.9 WV Code Chapter 16, Article 5Y, the Medication-Assisted Treatment Program Licensing Act, specifically allows for the use of telehealth as long as it is permitted under a practitioner's scope of practice. It is therefore requested that language be added to this definition allowing both face-to-face interactions as well as interactions via the use of telehealth. The utilization of telehealth to extend and expand health care services, including medication-assisted treatment, to residents of rural areas of West Virginia is a much needed means of increasing access to services in the pursuit of making a generational change in West Virginia's families and communities afflicted with opioid abuse.

Response

The Department has reviewed this comment, and no changes were made in response. Telehealth is defined in W.Va. Code § 16-5Y-2 and incorporated by reference into 64 CSR 12.

Comment

2.10 Definition of Counselor- It never states the educational requirements for this position. This could be read as either a Bachelor's level or Master's level provider. I would propose that if Bachelor's level providers are included, they be certified by the nationally recognized credential either (1) Alcohol and Drug Counselor, or (2) Advanced Alcohol and Drug Counselor.

Response

The Department has reviewed this comment. Existing provisions in the rule address this issue and, therefore, no changes were made.

Comment

2.18. For-Cause Inspection (n.b., Perhaps this should also include inspection to assure coding and billing procedures are in line with appropriate guidelines and the insurance companies' policies.)

Response

The Department has reviewed this comment. The changes do not meet the intent of the regulation, therefore; no changes were made in response.

Comment

2.20. Individualized Treatment Plan of Care/Treatment Plan- planning and goals should already be addressed in progress notes, which physicians and counselors are required to document for each encounter, per insurance requirements. Having treatment plans, in addition, would just create extra paperwork when the content is already included elsewhere in the patient's chart. (Suggestion: delete this requirement)

Response

The Department has reviewed this comment. The changes do not meet the intent of the regulation, therefore; no changes were made in response.

Comment

2.20 ITP to treatment strategy. Treatment strategy does not typically include all staff, client and therapist. Treatment strategy for focused level clients and treatment plan for coordinated care clients by definition.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

2.22 Indicators for dosage level. Typically a clinical evaluation is done by clinician and then if appears to meet criteria is then scheduled for doctor, therapist does not determine dosage.

Response

The Department has reviewed this comment and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

The word “staff” is too vague in §2.28 and staff should not participate in medical withdrawal decision.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

2.29. Medication Administration — (n.b., The use of "direct-observed therapy) for buprenorphine as a mono-product or as Suboxone is becoming more common in treatment facilities. Perhaps this definition can include that as one form of "medication administration.")

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

2.30. Mental Health Professional - This section does not mention psychiatrists who are mental health professionals as well as being physicians.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

2.32. Misuse or Non-Medical Use - We have concern with this definition as it implies that any medication prescribed by anyone other than a doctor is defined as misuse or non-medical use. The legislature, in its most recent session, provided APRNs independent practice authority including the authority to write prescriptions without a collaborative agreement. Currently other providers such as P.A.s and optometrists have certain prescriptive authority. We recommend dropping physician and inserting provider as provided under their scope of practice.

Response

2The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

2.32. Opioid Drug -- Any substance or drug having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug or substance having such addiction-forming or addiction-sustaining liability including, but not limited to, buprenorphine, fentanyl, heroin, hydrocodone, hydromorphone, methadone, morphine, codeine, Oxycontin, oxycodone, oxymorphone, and other medications that block the transmission of pain messages to the brain any natural, semi-synthetic or synthetic drug that acts primarily through any opioid receptor in the central nervous system.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

2.33. Opioid treatment services. Clarify intensive services. Regular outpatient therapy would be intensive individual and intensive group, not an ISP/IOP though.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

2.36. Physical Dependence -- A state of biologic adaption that is evidenced by a class-specific withdrawal syndrome when the substance is abruptly discontinued or the dose rapidly reduced, or by the administration of an antagonist. (n.b., Suggest following this definition with Physical Addiction?)

Response

The Department has reviewed this comment. Existing provisions in the rule address this issue and, therefore, no changes were made.

Comment

In §§ 2.38 and 14.1., the term “advance practice registered nurses” should read “advanced.” This term should be followed by the word “and” not “or.”

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

2.40 Plan of Ed. -- Clarify what constitutes Plan of Ed. Recommend agency trainings as part of staff training versus other means, physicians doing MAT have received training, therapists are trained in SA.

Response

The Department has reviewed this comment. Existing provisions in the rule address this issue and, therefore, no changes were made.

Comment

2.41. Positive Drug Screen -- Suggest defining "drug screen" first, describing the purpose/intention of the testing and perhaps comment on the "screening" or "point-of-care" level of testing and "LaVIS" or "confirmatory" levels of testing and perhaps mention that the tests may include urine, saliva, blood, and/or hair.

Response

The Department has reviewed this comment. Existing provisions in the rule address this issue and, therefore, no changes were made.

Section 4 – State Oversight Authority; Powers and Duties

Comment

4.2.a. We recommend this language be clarified to assure that any rule or regulation developed and implemented go through the legislative rule making process and that passage of this proposed rule as part of a DHHR omnibus rules bill during a legislative session does not provide DHHR the authority to promulgate rules independently of the legislature.

Response

The Department has reviewed this comment and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Section 5 – Certification; Approval and Exemptions

Comment

Consideration should be given to inserting the word “outpatient” or “office-based” before the words “medication-assisted treatment in §5.1.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

5.3.a We do at times keep patients on suboxone on CSU for more than 7 days especially when the patient has comorbid disorders being treated other than opioid use disorder. In order to accommodate these cases we think extending the 7 day limit is necessary.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Section 6 – Registration for OBMAT programs; Fees and Costs

Comment

In regard to fees, unreasonably high and indeterminate fees could seriously impede clinicians’ interest in providing OBMAT. Finding physicians who are willing to provide services to this group can be challenging enough without requiring large or unspecified fees. For programs with a small number of patients, the fee could be reduced or waived until they attain a certain number of patients. In determining the amount of the fees, the adjustment for consumer price index and reliance on number of registrants, as well as the unknown cost of the requisite inspection, seems unprecedented. Generally, licensure fees are set at a fixed amount, and the cost should include any necessary inspections. Further, charging twice as much for a renewal as compared to an initial registration seems counterintuitive.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

6.1 General Registration Provisions. Each office having to have a separate registration versus one registration per agency. Recommend that this be based perhaps on enrollment, size of program, for small programs this could be a hardship

Response

The Department has reviewed this comment and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

6.1.d OBMATs do not dispense medications. Omit.

Response

The Department has reviewed this comment and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

The words “unique to that program” in §6.1.e. are problematic and should be removed. Each of Acadia’s clinics is both an OTP and an OBOT with one physician covering both. Medical directors can also cover more than one location.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

Does §6.2. apply only to new OBMATs?

Response

The Department has reviewed this comment and no changes were made. Further, the rules applies to all OBMAT programs.

Comment

6.3. With the goal of increasing access to MAT, physicians who have multiple practices should not be penalized by having to register and pay separate fees for each site at which they prescribe.

Response

The Department has reviewed this comment and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

The annual renewal fee calculation in §6.3.a. is vague.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

Doctors will likely practice in multiple locations, so this should be addressed in Fees §6.3. instead of §§ 6.1.b. and c.

Response

The Department has reviewed this comment and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

The annual renewal fee in §6.3.a. is NOT based on the daily census of the program.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

Change the word “license” to “registration” in §6.3.a.2.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

69-12-6.3.a.3 – Renewal fee – For what is the \$500 fee adjusting? If the cost of applications/licenses is going to vary, it would be most logical to make it based on number of patients. It does not seem logical to charge very small practices the same fee that large practices pay. It has the potential to be a large deterrent for rural practices or practices with only a few patients in need of this type of service.

Example of proposed Renewal Fee schedule	
# of patients	Cost
1-5	\$50
6-20	\$75
21-50	\$100
51-100	\$125
101-200	\$200
201+	\$300

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

6.3.b - Is this standard practice for any other clinic, that there is an additional fee for inspections? I would think that is what the OBMAT registration fees should cover.

Response

The Department has reviewed this comment and no changes were made in response. This provision is standard practice for all clinics.

Comment

6.4.a. Initial registration. Is there to be no grandfathering? 12 months at a time. Suggest 36 months at a time.

Response

The Department has reviewed this comment and no changes were made. Further, this rule applies to all OBMAT programs.

Comment

6.5.a.1. It is recommended that the word "significantly" be added before the word "deficient" in order to establish a reasonable standard of review.

Response

The Department has reviewed this comment and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

6.5.a.2. State and Federal Standards. These seem more like OTP dispensing clinic requirements rather than OBMAT which might continue to be better served under the Behavioral Health Licensure as it has been when no dispensing is involved.

Response

The Department has reviewed this comment and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

6.5.a.5. Again, based on WV Code §16-5Y-5(c), if a program is CARF Accredited then one medical director may be designated to oversee all facilities, thus the medical director of a CARF Accredited program may not necessarily always be practicing at a specific program location. Therefore, the provision set forth in rule is in conflict with and creates a circumstance in which

the provision in rule exceeds what is provided in statute. A change in the language is recommended to conform to the provisions of the statute.

Response

The Department has reviewed this comment and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Section 7 – Administrative Organization and Management of OBMAT Programs

Comment

Admin Organization & Mgmt:

- This would be a non-billable position but would have to be needed to ensure compliance. Decrease regulations.
- We do not store meds – on site pharmacy does. This would not apply to us but the pharmacy?
- Medical Director to practice 75% of hours. Do not think it needs to be this high.
- Physician on call at all times. Is this necessary?
- 1-50 counselor ratio
- One hour of supervision to 20 hours of direct service for unlicensed or unsupervised staff. Less hours of supervision.
- 20 hours of initial training. Less hours of training.
- Two weeks of shadowing time. Less shadowing time.
- Must have a physician, or PA, or APRN or RN present during operation. Not needed if just doing therapy.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment. Please refer to additional specific comments and responses below.

Comment

7. Administrative Organization and Management of OBMAT Programs. (n.b., Again, impossible for a small or solo practice.)

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

7.1. Each OBMAT program shall identify a ~~program administrator~~, medical director, and, if applicable, a program administrator, program physician(s), and counseling staff.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

7.1 Medical Director and program physician. Can these be the same person?

Response

The Department has reviewed this comment and no changes were made. Further, there is no prohibition in the rule preventing a program physician serving as the Medical Director.

Comment

7.1. Both Chapter 1.6, Article 5Y, Medication-Assisted Treatment Program Licensing Act, and this rule allow counseling services to be provided by referral. Indeed, the comprehensive patient treatment desired may be accomplished through a collaborative arrangement. It should be noted that not all treatment elements have to be contained as part of the same program setting, even

though all elements have to be part of a treatment plan for the individual patient. Therefore it is requested that the identification of counseling staff be optional and not required. Once again, the express provision of the proposed rule exceeds the requirements of the underlying statute and could result in reduced access for those needing medication-assisted treatment for drug addiction.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

7.2. Program Administrator. The educational requirements listed are not particularly necessary as this is, in my experience, an administrative position. Clinical staff need the behavioral health / addiction background but ancillary staff need organizational and people skills.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

7.2.c.5. Security of med storage and safe handling. We do not dispense medication for MAT. Omit.

Response

The Department has reviewed this comment, and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

7.3. The proposed requirement that the medical director shall practice a certain number of hours per week could prevent many offices from functioning. There is no clinical or therapeutic reason for this requirement, and the DEA already provides regulatory guidance on this issue. It also would preclude the use of telemedicine or telepsychiatry, since the physician would not be “on site.” Telemedicine and telepsychiatry have been the conduit for successful treatment of many patients in our very rural state.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

7.3.b.1-7.3.b.3 According to the subdivisions contained in 7.3.b., in order for a physician to hold the position of medical director, he or she must obtain a DATA 2000 waiver and be either experienced or competent in substance use disorder or medication-assisted treatment. In order for a physician to receive his or her DATA 2000 waiver as required in 7.3.b.1, SAMSHA requires a physician to hold a certification in addiction medicine or to complete SAMSHA approved training in opioid addiction, either of which would certainly constitute a demonstration of experience or competence in substance use disorder treatment or medication-assisted treatment. In order to eliminate this redundancy, it is requested that subdivisions 7.3.b.2 and 7.3.b.3 be stricken, as the obtainment of a DATA 2000 waiver should indeed be considered sufficient evidence of experience and/or competence in substance use disorder or medication-assisted treatment.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

7.3.b.3. Written plan to obtain competence in SA MAT. If physician has DEA X and DATA 2000 is that not sufficient?

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

7.3.c.1. time frame for completion- there is not a specified time frame in which the plan to become competent should begin. This would allow the medical director to provide services and not start this program until close to the end of the 12-month period. (Suggestion: To begin within first 2 weeks or month of appointment/hiring)

Center

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

7.3.c.2. Probationary period of physician. Again I do not see how this is clear of what the training plan must be and who would have already met it other than those docs who have obtained DEA x, DATA 2000, etc.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

7.3.d.5. Basic and continuing ed. Need specifics of what would be required otherwise may be interpreted differently.

Response

The Department has reviewed this comment. Existing provisions in the rule address this issue and, therefore, no changes were made.

Comment

Requiring a medical director to practice 75 percent of the hours in which an OTP is operating in §7.3.e. is inconsistent with the statute and should be deleted from the rule. If this requirement remains, most OBMAT clinics will close. Likewise, the words “shall be present during all hours of operation and” should be stricken from §7.3.f.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

7.3.f. Present all hours? Does this include when therapy is occurring.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

7.3.f. Within 10 days after the withdrawal or termination of the medical director, the owner or owners of the program shall notify the secretary of the identity of another medical director for the program. During the interim, not to exceed 60 days, another licensed physician shall be present during all hours of operation, or immediately available by telephone or telemedicine, except in the event of an emergency or unforeseen event, and shall assume the duties of the medical director on a temporary basis until such time

as a new medical director is identified and begins work at the program. The interim physician may be another owner of the program or a program physician employed by or associated with the program.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

7.4.a. The OBMAT program may employ and use program physicians, physician extenders and other health care professionals working within their scope of practice who have received sufficient education, training, experience, or any combination thereof, to enable that person to perform the assigned functions. All physicians, nurses and other licensed professional care providers must comply with the credentialing requirements of their respective professions. The OBMAT program may only employ registered nurses, advance practice registered nurses and physician's assistants as physician extenders. (n.b., this conflicts with the definition of physician extenders.)

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

7.4.b.2.A enrollment in plan of education – There is no way for standardization the way it is currently written. Requiring that the education plan be approved by an addiction-based, nationally-recognized program/agency or approved CME's would allow for a more standardized plan with accountability.

Response

The Department has reviewed this comment and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

7.4.d. Present all hours? Again even when therapy is the only service at the specific time being provided? Typically the physician would not have to be present when therapy is provided.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

7.4.d. Staff expected to be present during hours of operation. Smaller county offices of BHCs may have medical staff present available only during certain days of the week. Include telehealth options for clinic days or crises during non-clinic days.

Response

The Department has reviewed this comment and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

7.4.e.3. Plans of education. Will need to know what is acceptable.

Response

The Department has reviewed this comment, and no changes were made.

Comment

7.5.a. Counseling through an OBMAT program shall be provided by counseling staff that meet the qualifications as described W.Va. Code § 16-5Y-5(d). (n.b. This is important. Where can that code be found?)

Response

The Department has reviewed this comment, and no changes were made. Further, W.Va. Code § 16-5Y-5(d) can be found on the state legislative website.

Comment

7.5.c. A ratio of 50 patients to 1 counselor is nowhere near enough, and I'm wondering what research these numbers are based from. In my current position, I see close to 100 patients within a mix of group therapy and individual therapy, and I can assure you that not only is that caseload manageable, but also I believe I provide effective care to each of those patients. Furthermore, our states does not have nearly enough counselors willing to treat patients with Substance Use Disorders that will fill the need the 50:1 ratio will inevitably require.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

7.5.d. Supervision requirements of unlicensed counselors. Current licensing requirements do not require BHC counselors to be licensed. Licensed or unlicensed counselors are required to have an hour of supervision once per month unless they are completing requirements for a license, and then the amount of supervision is prescribed by the licensing board. Allow BHCs to continue to follow rules established by Medicaid/OHFLAC.

Response

The Department has reviewed this comment, and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

7.5.f. training for new employees – training on addiction-related issues should have some type of standardization, as mentioned in previous comments. State Board-approved CEU's or ADC/AADC license would seem reasonable.

Response

The Department has reviewed this comment and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

7.5.g. exemption for experienced counselors – this is worded strangely. (Suggestion: An experienced counselor from another MAT program that is newly employed with an agency may be exempt from the mandatory initial training if they can provide documentation proving they have had a minimum of 20 hours of recent (within the past 2-3 years) addiction-specific training OR have more than 5 years of experience in addiction/recovery.)

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Section 8 – Environment and Operation of Office-Based Opioid Treatment Programs

Comment

We understand the law requires that, prior to directly billing a patient for any medication-assisted treatment, a physician's practice receive either a rejection of prior authorization, rejection of a submitted claim, or a written denial from a patient's insurer or West Virginia Medicaid denying coverage. However, we also understand the law gives the Secretary the authority to grant a waiver or variance from this requirement. We strongly support the granting of such waivers to solo practitioners and small group practices that do not have the infrastructure required to submit insurance claims. Further, we encourage

the Secretary to grant a waiver from this requirement to practices that treat patients who want to maintain confidentiality of their addiction treatment from their employer or insurer.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

Sections 8.5 and 8.6, which would require “programs” to develop and implement policies and procedures for infection control and community relations, seem unnecessary for OBMAT programs and more appropriate for OTPs. Such requirements not only further the stigmatization of patients with addiction, but amount to burdensome administrative paperwork requirements that do nothing to promote the quality of care offered by a practice. In fact, by devoting time and resources to documenting efforts to avoid community disruption and developing “policies and procedures for soliciting patient and community ideas about medication-assisted treatment,” physicians would be spending less time providing care, counseling patients and ensuring that their practices are meeting recommended clinical quality standards. A medical practice should be abiding by nationally recognized clinical practice guidelines, not community ideas of what treatment should be. It should be attentive to its patients’ concerns and needs rather than those of non-patients who may hold stigmatizing views of persons with addiction. We recommend striking this section of the proposed rule to minimize unnecessary administrative requirements that do not contribute to treatment quality and avoid giving official credence to non-medical opinions about addiction treatment.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

Sections 8 and 9 Facility Construction and Renovations; Life Safety Policies and Procedures. These sections included a lot of language that related to OTP, no OBMAT.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

8.1 Service Operation Schedule. Regulation of hours of operation. Regulations seem pertinent to prescribers of Methadone. Outpatient BHC hours for OBMAT should be less restrictive - not practical for all locations.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

The word “or in §8.1.a. should be corrected to “of” and the words “if needed” should be added to the end of the sentence.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

8.1.c.1. Intent to close on Sundays notice. This applies to OTPs that operate 7 days a week, office based does not.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

Dosing programs or take-homes in §§ 8.1.c.2., 30.11.b., and 33.3.c. don't apply to OBMATs.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

8.1.c.2. The program shall establish procedures for emergency access to dosing information 24 hours a day, seven days a week. This information may be provide [sic] via an answering service or other electronic measure. Information needed includes the patient's last dosing time and date, and dose. (n.b., It is not entirely clear what this section is saying.)

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

8.2 - Medicare should be added to this list.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

8.2. Payments for services rendered may be made either by West Virginia Medicaid, Medicare, private insurance, or by cash ~~as described in 8.2.d.~~

~~8.2.a. The OBMAT program shall be eligible for, and not prohibited from, enrollment with West Virginia Medicaid and other private insurance.~~

~~8.2.b. Prior to directly billing a patient for any opioid treatment, the OBMAT program must receive either a rejection of prior authorization, or rejection of a submitted claim or a written denial from a patient's insurer or West Virginia Medicaid denying coverage for such treatment.~~

8.2.e.a. The OBMAT program shall document in the patient's record any rejection of prior authorization, rejection of a submitted claim for written denial from a patient's insurer or West Virginia Medicaid denying coverage for opioid treatment. The OBMAT program shall also clearly document in the patient's record if the patient has no insurance or has voluntarily and with full knowledge of the financial obligations, including all treatment costs, requested a claim not be submitted to their insurer or West Virginia Medicaid. When any instance described in this section regarding direct billing and acceptance of cash payments from a patient occurs, the OBMAT program shall clearly document in the patient's record the rationale and medical necessity for acceptance into the program.

8.2.d.b. The OBMAT program may directly bill and accept cash payments from a patient ~~only after~~ if the requirements of sections 8.2.a., ~~8.2.b. and 8.2.e.~~ herein, have been fulfilled and documented, or if the secretary has granted a waiver of this requirement.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

8.2.a-8.2.d. WV Code §16-5Y-5(e) states, "Prior to directly billing a patient for any medication-assisted treatment, a medication-assisted treatment program must receive either a rejection of prior authorization, rejection of a submitted claim, or a written denial from a patient's insurer or West Virginia Medicaid denying coverage for such treatment: **Provided, That the Secretary may grant a variance from this requirement pursuant to section six of this article [emphasis added].**" This rule makes no reference to the payment variance option provided for in code and therefore further restricts the provisions of law beyond what the law provides. A rule may not be inconsistent with the underlying law. In this case the rule is presuming that every patient is either covered by Medicaid, private insurance or chooses to ignore the right, for whatever reason, to be directly billed for the services extended. Ohio Valley Physicians treats any number of patients who receive employer-sponsored insurance coverage. These patients understandably may prefer to pay for substance abuse treatment services out of pocket so as not to be labeled by an employer and perhaps even the community. Therefore, the variance option provided for in code is critical for some patients of Ohio Valley Physicians and is worthy of being reiterated in rule. Without this provision, the practical effect is likely to drive some patients out of treatment or, in other instances, cause them to seek treatment in distant locations outside the local area of their residence in order to avoid adverse notoriety they would hope to avoid. This is particularly true in border regions of our state where patients may choose to seek treatment in adjoining states and reduce the market opportunities for West Virginia clinics needed to sustain a sufficient patient population for not only medication-assisted treatment, but for other healthcare services as well.

Response

The Department has reviewed this comment and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

Sections 8.2.b and 8.2.c are in conflict with each other. Our practice operates on a cash only basis and to purchase billing software for this would be cost prohibitive. Also, most of our patients desire confidentiality from sharing of this sensitive information with their employer or insurer. In addition, it is our understanding that an office is not allowed to have patients pay cash if he/she is on Medicaid and therefore we do not accept patients who are insured through Medicaid.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

8.2.c – documentation of payment, self pay – This still would allow providers to claim they accept insurance, but have every patient just sign a waiver form that says they prefer to private-pay rather than go through the insurance. (Suggestions: (1) providers must report what % of clients are private pay, (2) A minimum of 30% [randomly chosen] of clients must be billed through insurance and/or state Medicaid, unless they have fewer than 5 [again, randomly chosen] patients).

Response

The Department has reviewed this comment and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

8.2.c. Need to make clear this is ONLY if payment will be cash basis, otherwise it is an unneeded. The OBMAT program shall document in the patient's record any rejection of prior authorization, rejection of a submitted claim for written denial from a patient's insurer or West Virginia Medicaid denying coverage for opioid treatment if the OBMAT program intends to collect payment on a cash basis.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

8.2.c This is not applicable when electronic records are used.

Recommendation: 8.3.c. A secure room and lockable equipment for patient records or other appropriate security mechanisms for electronic records;

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

8.3.a. – 8.3.g. Several of the provisions contained in subsection 8.3 either do not apply to the treatment offered by Ohio Valley Physicians or are difficult to determine. First, the language in 8.3.c appears to be grossly outdated as it fails to recognize the prolific use of electronic medical records. Next, 8.3.d requires the OMBAT program to have a private office or area for counseling. As mentioned previously, both the Medication-Assisted Treatment Program Licensing Act as well as the proposed OBMAT rule allow for the referral of counseling services. Therefore, Ohio Valley Physicians should not be required to have private counseling space on site. Second, while Methadone may require daily on-site dispensing, the types of treatment provided by Ohio Valley Physicians do not. In fact, as already demonstrated, several provisions in the rule referring to the dispensing of medications have apparently been lifted from Methadone regulations and do not apply to OBMAT programs. OBMAT programs do not store medications on site because they do not dispense medications, nor do they require the same level of oversight as Methadone clinics. Therefore the provisions of 8.3.e do not apply in instances in which the office based treatment is distinguishable from those instances in which daily on-site dispensing occur. As to 8.3.f and 8.3.g, sufficient restrooms and adequate parking are undefined subjective requirements. How many restrooms are sufficient and how many parking spaces are adequate? Frankly, it is all relative to the patient load, scheduling and local logistics in terms of parking garages or parking lots in the vicinity should the office facility lot become full for some reason. Once again, this would seem to be a rule directed at sites where daily dispensing occurs rather than an office based facility such as those operated by Ohio Valley Physicians. In some jurisdictions, local zoning ordinances dictate required parking, and local public health ordinances would address bathroom requirements. In those cases subdivisions 8.3.f and 8.3.g are redundant and potentially conflictive with local zoning and public health laws in local jurisdictions.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

8.5 Infection control. Universal Precautions. Would the usual universal precautions trainings currently done not suffice?

Response

The Department has reviewed this comment and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

8.5 and 8.6 – The Medical Director and Program Coordinator should be well equipped to respond to community concerns as required. The idea that “policies and procedures for soliciting patient and community ideas about medication-assisted treatment” would not be beneficial to our patients. The community should be educated on addiction by medically trained professionals, not invited to give non-

medical opinions as to how addiction should be treated. This could reinforce the negative stigma associated with treatment and should be deleted.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

8.6 This section appears to be written to address the concerns with methadone and note that there are nuisance and zoning laws that deal with what this section wants to accomplish. This will require at least one new staff person and will be expensive. This is not required of physical health and is discriminatory towards mental health, continuing to foster an unfortunate stigma.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

8.6 Community relations. Community education/disruptions/diversions. Random for medication counts to ensure being taken currently and to decrease diversion, also can check levels if suspicions, again with small clinics there is not an issue with loitering, disruption, we are not an OTP we do not have clients standing in line to dose, we do not dispense in OBMAT.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

8.7. This provision is yet another example of trying to force Methadone regulations on OBMAT programs. Again, OBMATs do not dispense medications; medical professionals simply write the prescription deemed medically necessary to treat the patient and then the patient has the prescription filled at the pharmacy of his or her choice. There is no daily dosing at the OBMAT site and therefore this provision is not applicable and should be stricken.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Section 9 – Facility Construction and Renovations; Life Safety Policies and Procedures

Comment

The provisions of this section seem more pertinent to OTPs, and we recommend that the section be deleted in its entirety. Subsections 9.1. and 9.2. refer to construction of OBMAT facilities, which might apply to an OTP seeking to expand its practice but does not seem relevant for existing OBMAT programs. Subsection 9.5 pertains to facilities which dispense medications, which are classified as OTPs, and it does not apply to OBMAT programs. It would be unprecedented for the DHHR to require a private physician practice to submit architectural drawings for approval prior to construction or expansion of their practice.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

Throughout this section the word "dose" and "administered" appear. OMBAT does not dispense medication. We recommend that sections 9.5 and 9.6 be rewritten to be reflective of what an OMBAT actually does versus, e.g. a methadone Clinic.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

Existing clinics should be grandfathered in regarding ADA compliance in §9.3.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

9.5 Life Safety Policies and Procedures. This section appears to be for OTP. Omit.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

The words “and dosage levels verified” may be deleted from §9.6.a. since that information may be obtained from the controlled substance monitoring database.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

9.6.a. The requirement to maintain 7 day-per-week access to "designated" program staff for an OBMAT program is both costly and unnecessary. It has a major impact on the business model of the physician based practice. The physician based treatment regimen is based on appointments scheduled by patients. It is not a circumstance of daily dispensing of Methadone as this provision in rule would seem to imply to be the case. Verification of dosage levels is dictated by that which was prescribed previously in the timeline of patient care.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Section 11 – Plans of Correction**Comment**

11.1.c. plans of correction – Who is the governing body? Might be helpful to clarify is this the medical director or administrator, or someone else.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Section 12 – Waivers and Variances**Comment**

12.1.-12.3. There are two specific variances addressed in the Medication-Assisted Treatment Program Licensing Act which are not referenced in this rule. They are as follows: §16-5Y-5(e) The medication-assisted treatment program shall be eligible for, and not prohibited from, enrollment with West Virginia Medicaid and other private insurance. Prior to directly billing a patient for any medication-assisted treatment, a medication-assisted treatment program must receive either a rejection of prior authorization, rejection of a submitted claim, or a written denial from a patient's

insurer or West Virginia Medicaid denying coverage for such treatment: Provided, That the Secretary may grant a variance from this requirement pursuant to section six of this article. The program shall also document whether a patient has no insurance. At the option of the medication-assisted treatment program, treatment may commence prior to billing. §16-5Y-6(c) Medication-assisted treatment programs shall not be located within one-half mile of a public or private licensed day care center or public or private K12 school. Existing medication-assisted treatment programs, including both opioid treatment programs and office based medication-assisted treatment programs that are located within one-half mile of a public or private licensed day care center or public or private K-12 school, shall be granted a variance, provided that the facility demonstrates adequate patient population controls and that it may otherwise meet the requirements of this article and the rules promulgated pursuant to this article. It is the request of Ohio Valley Physicians that these specific variances are at the very least referenced in the Waivers and Variances section of this rule. Otherwise, the rule makes another attempt at intrusion on the authority of the legislature by an executive branch agency by limiting implementation in rule of the express provisions of law legislated by the legislature and signed into law by the governor.

Response

The Department has reviewed this comment, and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

12.1. Physicians may obtain a waiver from the requirements set forth in this chapter if they treat 30 or fewer of the patients in their practice with OBMAT.

Response

The Department has reviewed this comment, and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

12.2. Qualified physicians may obtain a waiver from the requirements set forth in this chapter, regardless of the number of patients in their practice treated with OBMAT, up to the maximum allowed by law, so long as they hold a current WV medical license, a valid DEA registration number, and meet one or more of the following conditions:

Response

The Department has reviewed this comment, and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

12.2.a. The physician holds a board certification in addiction psychiatry or addiction medicine from the American Board of Medical Specialties.

12.2.b. The physician holds an addiction certification or board certification from the American Society of Addiction Medicine or the American Board of Addiction Medicine.

12.2.c. The physician holds a board certification in addiction medicine from the American Osteopathic Association.

Response

The Department has reviewed this comment, and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

12.3. Physicians may apply for and obtain waivers or variances from the requirements in this rule, for reasons other than those enumerated above, by making written application to the secretary, explaining the rationale for the request, and describing how the physician will maintain quality of care for his or her OBMAT patients if the waiver or variance is granted.

Response

The Department has reviewed this comment, and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Section 13 – Reports and Records

Comment

This entire section is problematic. It was not required under SB 454, which stated that reporting requirements only applied to providers who dispensed medications to patients, and therefore does not include OBMAT providers. OBMAT providers would not be able to comply with the onerous requirements in this section. Private clinics do not have the ability to track this kind of data with any credibility; the requirements are consistent with grant-supported, research-level data collection and are not feasible in private practice.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

This section requires a significant number of data reports that need captured and reported by an OMBAT program. We agree that data should be kept and reported however, the required information is excessive. We would ask that a workgroup be established to determine what data is needed to be reported on that will actually be read and acted on. For many of our members the experience has been that data collection and reporting is required in rules but none of it is ever used. Businesses should not be burdened with the cost of unneeded data collection and reporting.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

If the goal is to make more treatment available, the length, complexity, and prescriptiveness of the proposed rules are likely to discourage OBMATs. Many people who need treatment have Medicaid, which will discourage practices without coding, billing, and utilization review staff. The reports and records requirement of §13 will, by itself, prevent practitioners from opening – or continuing to operate – an OBMAT. As it is written, each OBMAT would require a grant funded research position to collect and make such data usable.

Response

The Department has reviewed this comment, and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

13 Would like to have providers report source of payment: insurance and cash/private pay.

Response

The Department has reviewed this comment, and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

Quarterly reporting in §13.1 is too time consuming; there is not a two-year treatment time table.

Response

The Department has reviewed this comment, and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

13.1.c. Perhaps a better way of stating 13.1.c would be: "A report of an inspection or investigation, whether initiated by the secretary or pursuant to what is determined to be a prima facie violation of statute or rule, may be made public and shall also state whether a plan of correction has been submitted to or approved by the secretary." In the event a spurious complaint is made against an OBMAT program which ultimately proves to be false or even maliciously cast, it would be an injustice to the program to make said complaint public if the complaint is found to be unsubstantiated. The mere accusation without some level of merit has the potential to harm the reputation of a respectable facility and bring harm to a program achieving success in the battle to arrest drug addiction in West Virginia. Caution needs to be observed and provisions made in the language of the rule to protect the essential element of client confidentiality.

Response

The Department has reviewed this comment and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

13.2. Statistical reporting in such detail is usually required by a grant-supported facility such as an FQHC, not a private clinic. The detail in this section is excessive, as is the frequency. This information (why the patient is discharged, time in treatment, etc.) is available in the patient charting if needed. A non-government clinic such as most OBMAT facilities do not participate in research, thus such detailed data is not usually kept separately. Further, reporting the information as outlined here would be a breach of patient confidentiality.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

13.2 Statistical Reports and Records. Requirement for quarterly statistical reports. Currently data required is determined by licensing and Statements of Work from BBHF. Exempt licensed BHCs from additional data required or build into current methods of data provision.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

13.2. While Ohio Valley Physicians will gladly submit the statistical information requested in 13.2 to the secretary for agency review and compilation, due to the nature of the information, we must ask that any reports generated by Ohio Valley Physicians containing these statistics not be available for public review other than in the aggregate of such information reported by all OBMAT programs. Otherwise, such information as reported by individual OBMAT programs may involve disclosure of proprietary competitive business information. It is therefore requested that a provision be added clarifying that the statistical reports and records referenced in subsection 13.2 will not be available to the public.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

13.2.a.2 We cannot know who may have received treatment from other providers. The number of patients who have been continually receiving medication-assisted treatment from the OBMAT provider in excess of two years, including the total number of months of treatment for each of these patients;

Response

The Department has reviewed this comment, and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

13.2.a.7 There is no section 33.6

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

In nine years, we have never had an appallingly stereotypical adverse event listed in §13.3.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific amendment.

Comment

13.3. In terms of the provisions of 13.3.a and 13.3.b, it would seem prudent to alter the language of 13.3.b slightly to impose a more realistic duty on the OBMAT program. It would be a more manageable scenario for all if it read as follows: "Adverse events or incidents are defined as an event known to the OBMAT medical director which may involve:" Otherwise many of the items set forth in items 13.3.b.1, 2 and 3 and those items set forth in 13.3.c may be items never known to the OBMAT program. For instance, how would the program know whether "harm to family members or others from ingesting a patient's medication" had occurred or by what means (theft for example) a patient's medication had become possessed by a third party. Similarly, the rule as written would seem to impose an obligation on the OBMAT program to know if there was an incident in which there was a "potentially lethal patient suicide attempt." If the suicide attempt occurred in a remote location and was never reported to the OBMAT program, there is no way the program should be accountable for reporting such as it would have no way of knowing. Additionally, the likelihood of an incident to cause community concern is impossible to determine and difficult to report. How would one know and how could one be held accountable under the rule of law in such a circumstance? The list of events and incidents should be reviewed to better determine what an OBMAT program can realistically be responsible for documenting and revisions should be made to restrict the obligation of reporting as to those matters for which the program has actual knowledge. Once again caution should be observed to avoid violations of patient confidentiality.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

13.3.c.1. Again refers to OTP OBMAT does not dispense. Omit.

Response

The Department has reviewed this comment, and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

13.3.f. To the extent this is a self-reporting of facts and circumstances which may possibly involve illegalities (incidents or adverse events), one must be extremely careful. In addition to likely compromising patient confidentiality or perhaps reporting alleged criminal conduct, great risk of liability is a potential unintended consequence on OBMAT programs and perhaps others.

Response

The Department has reviewed this comment, and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

OBMATs find out about deaths in §13.3.g. later and wait for medical examiner report.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Section 14 – Staff Training and Credentialing**Comment**

In §§ 2.38 and 14.1., the term “advance practice registered nurses” should read “advanced.” This term should be followed by the word “and” not “or.”

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

14.1 credentialing – as previously mentioned, so many hours should be addiction/treatment-specific. This would also be another opportunity to clarify what level of education the counselors should have.

Response

The Department has reviewed this comment and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

The hiring process is business/owner specific and should not be dictated by §14.3.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Section 15 – Risk Management**Comment**

Risk Management: Individualized treatment plan. Can we use strategy instead?

Strength of dosage should decrease over time. Conflicts with 15.1.d.4. patient may be maintained on the med as he or she desires.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

There is no evidence or justification for the statement in 15.1.d.2.A., and it is contrary to current standard of care. It should be deleted. In fact, the entire subsection 15.1.d is overly prescriptive and interferes with physicians’ ability to practice unencumbered under their medical licenses. 15.1.b. covers the provisions in 15.1.d., so we recommend that the entire subsection 15.1.d could be deleted.

~~15.1.d.2.A. The strength of maintenance doses of medication-assisted treatment medications should decrease over time, as clinically indicated; and~~

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

15.1.d.3. Individualized tx plans. Suggest tx strategy or individualized tx plan.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

Health care workers are already mandatory reporters for abuse, so §15.2. is unnecessary.

Response

The Department has reviewed this comment. The proposed change does not meet the intent of the regulation and, therefore, no changes were made.

Comment

Nor does the concept of due process in §15.4.b. apply to a private business.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Section 16 – Medication Security, Storage, Administration and Documentation**Comment**

This section is another which we believe is not necessary or appropriate for an OBMAT program. The section should be completely rewritten to reflect OBMAT programs do not dispense medication. There needs to be documentation but it needs to be appropriate.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

This section seems to apply to OTPs and not to OBMATs; in fact, 16.5 states “An OBMAT program and its physicians shall not dispense or administer medication-assisted treatment drugs on site.” Since OBMATs do not dispense or administer medications on site, then the entire section is unnecessary and should be deleted.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

Medication security §§ 16.1. and 16.2. apply to OTPs, and seems counter to §16.5. Instead, write “Each OBMAT program that chooses to obtain and store medication for usage in their OBMAT program shall develop and implement policies...”

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

Only a licensed provider with DATA 2000 waiver can determine dosage, so the term “staff” in §16.4.a. is too broad.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

16.4.a. We believe this proposed language is more applicable for methadone programs given the references to dosages. In an OBMAT program the provider issues a prescription that is filled by the patient at a pharmacy where the pharmacy provides counseling on the medication. We also recommend dropping "and individualized treatment plan of care" from the language. We believe that prescription-related information should be maintained in the patient chart as it is the most up-to-date patient record which eliminates confusion.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

The words “dose,” “dosages” and “dosing” in §§ 16.4.a., 20.11. and 34.5.d.2. should be changed to “prescription” since no medications are administered on site.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

16.5. There may be OBMAT providers that have residential substance programs where providers deliver medication that is prescribed by a doctor and filled by a pharmacy to a resident. The resident self-administers the medication. This prohibition could have significant impact on these residential programs. The language needs to be modified and rewritten to allow these facilities to provide services. In addition, OBMAT providers may also have short term detox programs where they do dispense Buprenorphine. These are short term programs, generally under 30 days, following which the patient is referred to an OBMAT program. The proposed rule should recognize these current programs not negatively impact them with further requirements.

Response

The Department has reviewed this comment and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

16.7 Rx info is it necessary to require dx, data 2000 and OBMAT license number? Remove dx, data 2000 and OBMAT license number.

Response

The Department has reviewed this comment and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Section 17 – Continuous Quality Improvement Policies, Diversion Control Plan**Comment**

Much of the language in this section applies to OTPs but is not applicable to OBMAT programs (e.g., “take home doses”). Further, “national outcome studies” are only required for OTPs, not OBMATs, and they would be prohibitively expensive for OBMAT providers. We recommend that the section be

deleted, except for the following provisions.

17.1. Each OBMAT program shall develop, implement and maintain current quality assurance and quality control plans that include provisions for:

17.1.a. Regular and continuous staff education;

17.1.~~e.b.~~ A service delivery assessment which, at a minimum, shall evaluate appropriateness of the individualized treatment plan and services delivered, completeness of documentation in patients; records and quality of and participation in staff training programs, linkage to a utilization of primary care and other out-of-program services, and availability of services and medications for other conditions;

17.1.~~g.c.~~ An ongoing assessment, measurement and monitoring of patient outcomes, treatment outcomes and the various processes including, but not limited to:

17.1.~~g.c.~~1. Reduction or elimination of the patient's use of illicit opioids, illicit drugs and the problematic use of licit drugs;

17.1.~~g.c.~~2. Reduction or elimination of associated criminal activities;

17.1.~~g.c.~~3. Reduction of the patient's behaviors contributing to the spread of infectious diseases;

17.1.~~g.c.~~4. Improvement of quality of life through the restoration of physical and behavioral health and functional status, including employment or volunteerism, as may be appropriate; and

~~17.4.2. An OBMAT program shall maintain a current "Diversion Control Plan" (DCP) as part of its quality assurance programs that contains specific measures to reduce the possibility of diversion of controlled substances from legitimate treatment use. The DCP shall assign specific responsibility to the medical and administrative staff of the OBMAT program for carrying out the diversion control measures and functions described in the DCP. Each OBMAT shall have a plan to manage medication diversion as part of its policy and procedures.~~

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

17.1.c. Tx. Plan. Needs to say tx plan or tx strategy.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

Annual surveys in §§ 17.1.e. and 17.2. will likely reveal negative patient satisfaction

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

17.1.g. Outcomes monitoring. This can be done and some of these outcomes are already in place, however, it still looks very much like OTP, refine outcomes specific to OBMAT.

Response

The Department has reviewed this comment. The proposed change does not meet the intent of the regulation and, therefore, no changes were made.

Comment

17.3 Additional quality improvement outcomes studies by state oversight. Need to know specifically what the outcomes measured would be to see if we have the capability to collect data requested.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

17.4 Diversion Control Plan – there is no mention of this being updated periodically. Might be reasonable to have it revisited every 2 years

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

17.4.b. DCP and tracking. Currently we call clients in for random medication counts to ensure they are taking medication correctly, have the correct amt., etc., what would help is if the pharmacies in the state were required to list the numbers on each film package distributed to help ensure the meds brought for counts are the clients. For tracking it is documented in the client's chart if there has been any diversion etc., is a separate log really necessary? Diversion is typically grounds for D/C.

Response

The Department has reviewed this comment, and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Section 18 – Patient Rights

Comment

18 – Patients taking part in OBMAT programs should be subject to the standard of care that applies to other practices. They should be informed of their rights and responsibilities and the grievance process of the program. These should be reviewed and signed and they should have a copy. Having it displayed in patient area is not expected in other doctor's offices and seems like overkill, and may even encourage litigiousness. 18.1.i. – while a program should make referral to appropriate care when a person is denied admission, that care may not be another OBMAT. Usually, if they are denied, it is because the provider feels they need a more intense level of care or are not a good candidate for OBMAT. Otherwise, they would not have been denied. Rather than putting the reason for denial in writing, it would be more beneficial to put the recommendation for appropriate treatment in writing. Further, there is absolutely no indication to give them a written "acceptance" letter or a copy of their initial assessment. This is never expected in any other physician's office.

Response

The Department has reviewed this comment and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

18.1 License requirements for counselors. BHCs do not have a requirement currently that counselors must have licenses to practice. Allow BHCs to continue to follow Medicaid requirements.

Response

The Department has reviewed this comment and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

18.1.c. Individualized plan of care. Again needs to also say tx strategy.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

18.1.c. Requirement for a Treatment Plan and that it be reviewed every 90 days. Currently only Residential Program participants receiving MAT must have a treatment plan; under Medicaid Rehab regulations, those patients seen in less intensive outpatient modalities have to have a treatment strategy. Allow BHCs to follow Medicaid regulations regarding treatment plans.

Response

The Department has reviewed this comment. The proposed change does not meet the intent of the regulation and, therefore, no changes were made.

Comment

18.1.d. Schedule to receive medications. Currently we have adopted the Medicaid guidelines of time in tx and progress for how often they are seen to receive their tx, i.e., weekly, bi-weekly, etc. would that not work to continue in that way?

Response

The Department has reviewed these comments and no changes were made. These regulations are the minimum requirements for an OBMAT program. There is no prohibition on additional treatment visits.

Comment

Referrals in §18.1.i. will force providers to assume care.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

18.1.i. Provision of written assessment to client. It is usual/customary to provide the written assessment to a client or other entity only upon request and with written consent from the client. Continue current process as is.

Response

The Department has reviewed this comment and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

18.1.i. To be given a copy, upon request, of the initial assessment, written acceptance into the program; or, in the case of denial of admission, a full explanation as to the basis of the denial, and a referral to another OBMAT program based upon the results of the initial assessment. We recommend adding "upon request" to this provision.

Response

The Department has reviewed this comment and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

Substitute “protection from other patients disruptive actions or behavior” for “who act out” in §18.1.n.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

Grievances should be handled through the formal complaint procedures at the state boards of medicine rather than as outlined in §18.2

Response

The Department has reviewed this comment and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Section 19 – Patient Records**Comment**

19. I agree that a physical exam at an initial assessment is appropriate to look for complications of drug use that could be acutely harmful or impact treatment. It does not usually need to be repeated every 90 days. Each patient should have a primary care physician for routine physical exams. There is also no need for a full biopsychosocial evaluation be repeated every 90 days. With the frequent medical and counseling sessions, any pertinent biopsychosocial changes will be noted in the progress notes.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

19.7.b. Documentation of program compliance with the program's policy regarding prevention of multiple admissions; (n.b., What does this mean? Multiple admissions to this OBMAT, or other OBMATs or other treatment facilities?)

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment. Further, multiple admissions refers to multiple different programs.

Comment

19.7.c. initial assessment report- by whom is this provided? The doctor? The counselor? A case worker? If this is by the counselor, it could be combined with 19.7.d.

Response

The Department has reviewed this comment. Existing provisions in the rule address this issue and, therefore, no changes were made.

Comment

19.7.e. I agree that a physical and biopsychosocial assessment is vital to complete at the start of a patient's treatment with us. However, I haven't seen any research that suggests that completing an official biopsychosocial assessment every 90 days is necessary. While in treatment, we are engaging patients at every single visit and gathering information on what is taking place for them on a medical, emotional, environmental and spiritual level. So this official assessment is necessary. This is brought up again at 25.4.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

Rewording is required for §19.7.f. regarding physical exams, which aren't usually done in an OBMAT.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

19.7.i and 19.7.j. Tx plans, take home medications. Again this is OTP regs, the language is straight out of OTP. Clients in OBMAT have tx strategies or treatment plans dependent upon what all services are appropriate, OTPs do a tx plan on every client.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

19.7.k. report of treatment process – take home medications is not relevant. Quantity of medication or duration of script (1 day, 3 days, 1 week, 1 month, etc) may be more appropriate language. (Suggestion: remove take home medication privileges).

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

19.7.1. Coordination of care agreements are not currently required when the physician and counselor are employed by the same organization. We recommend the following change:

Coordination of care agreements when applicable signed by the patient, program physician and primary counselor

Response

The Department has reviewed this comment and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

19.7.m. Good faith effort to check dual enrollment. Again this is OTP, in OTP that is necessary because they would not be on a BOP due to not getting an rx, however, OBMAT utilizes BOP because they would be getting an rx.

Response

The Department has reviewed this comment and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

19.7.p. Treatment Plan. Medicaid requires that clients in low intensity outpatient programs are required to have a treatment strategy, not a written treatment plan. Continue as required by Medicaid.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

Details regarding travel and employment in §19.7.q. are unclear.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment. This section details what is required to be included in patient records.

Comment

Counselor and/or medical staff in §19.8.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

19.8.b. This contradicts 26.12, where it states documentation needs to be done within 72 hours. Centers for Medicare and Medicaid Services have not defined a time for entry completion, but instead have this, “The service should be documented during, or as soon as practicable after it is provided in order to maintain an accurate medical record.”

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Section 20 – Pre-Admission Assessment; Admission Criteria and Admission Process

Comment

We recommend including the American Society of Addiction Medicine’s (ASAM) criteria as acceptable and preferred criteria to use for assessing a patient and determining the appropriate level of care. ASAM’s treatment criteria provide separate placement criteria for adolescents and adults to create comprehensive and individualized treatment plans. Adolescent and adult treatment plans are developed through a multidimensional patient assessment over five broad levels of treatment – including outpatient treatment – that are based on the degree of direct medical management provided, the structure, safety and security provided and the intensity of treatment services provided.

20.2. Any individual seeking admittance to the OBMAT program shall undergo a pre-admission initial assessment in order to determine whether the person meets the criteria for admission to an OBMAT program. The initial assessment, consisting of ~~a physical examination and~~ an intake screening, shall be conducted by the medical director, an approved program physician or a supervised physician extender. The initial assessment shall focus on the individual’s eligibility and need for treatment and shall provide indicators for initial dosage level, if required and if admission is determined appropriate. The determination of admission eligibility shall be made using accepted medical criteria such as those listed in the latest approved version of the Diagnostic and Statistical Manual for Mental Disorders.

20.3. The initial physical assessment shall include documentation of:

~~20.3.a. A brief physical examination;~~

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

20.2 Requirement for initial screening/physical examination. Currently, consumers having an initial assessment for MAT are screened by a qualified, trained clinician. If the consumer meets qualifications for MAT, then a contract is reviewed and signed, lab tests re ordered and the consumer will have a physical examination arranged. Pertinent medical records will be requested. Then, all those results are reviewed by the physician who sees the consumer to determine whether MAT is appropriate. Allow BHCs to determine patient flow procedures

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

The items in §§ 20.3.b. through m. are what you want to leave for the comprehensive assessment.

Response

The Department has reviewed this comment, and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

20.3.g. Screen for substances as determined by community standards. We currently do an 11 panel uds define community standards.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

20.3.i. Check dual enrollment. Again the BOP is the best way to do that in OBMAT it would be helpful if all BOPs nationwide were linked, it is difficult if not impossible to check BOP on neighboring states except Ohio which we are currently able to check along with WV.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

20.20 Requirements for logging non-admissions. Unless consumer has a record in EMR, tracking produces undue burden on BHCs. Provide exemption for BHCs.

Response

The Department has reviewed this comment and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

20.21.a. Requiring an OBMAT program to treat a patient is not good policy, regardless of the requirements that the patient meets. Not having the option to refuse a particular patient is potentially harmful to the OBMAT program to which transfer is being made. It is potentially harmful on various levels. Medical care providers may not be forced to treat patients unless in an emergency situation. There may be any number of reasons that a provider would not want to accept a patient, including a preexisting relationship which failed for whatever reason, distrust of the patient by the program staff, patient's lack of insurance and/or inability to pay for service, patient's history of criminal activity or violence, which makes them unsuitable to co-exist with others in the program setting. It is strongly suggested that the word "shall" in 20.21.a. be stricken and replaced with the word "may."

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Section 21 – Multiple Program Enrollments

Comment

Multiple Program Enrollments: Check for other program involvement. Time consuming.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

21.1. Tx at other facilities. Currently a client has the right to seek MAT at a treating physician and receive therapy at any agency of their choice, they only receive meds at one practice but are free to seek therapy where they choose, therefore, it would be difficult to enforce this. Clarify that this would be receive a prescription for MAT at only one program.

Response

The Department has reviewed this comment, and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

21.2. It is nearly impossible for a medical services provider to check the records of every OBMAT program within a 100 mile radius, as that provider is unlikely to even know of the existence of any and all OBMAT programs. This is particularly true of programs operating on the state's borders. By way of example, from Morgantown, WV to Pittsburgh, PA the distance is only 75.1 miles with any number of Pittsburgh suburbs in between. From Parkersburg, WV to the edge of Columbus, Ohio the distance is nearly 100 miles with various and sundry communities in between. From Charles Town, WV to Baltimore, MD the distance is 75.7 miles with significant sized communities such as Frederick, MD, Hagerstown, MD, Cumberland MD and Leesburg, VA even closer. From Charles Town to Washington, DC, the distance is only 63.3 miles and the densely populated area of northern Virginia in between. From Lewisburg, WV to Roanoke, VA the distance is only 86.5 miles. The capacity for an OBMAT program to begin to know where other treatment programs are operating is an unrealistic expectation. As an alternative and more meaningful information resource, it is recommended that the program be required to access the Controlled Substance Monitoring Database as a means of determining if the patient is receiving substance abuse treatment medications from another prescriber.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Section 22 – Controlled Substances Monitoring Program Database

Comment

22. Most of us routinely check a board of pharmacy report on admission, and at least every three months. This may be done more often if there is reason to believe that a patient is filling unapproved controlled medications. It is usually not necessary to check it more often. (The rule currently requires it after 30 days of treatment and after any positive test).

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

Add the words “or their designee” after the words “program physicians” in §22.2.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Section 24 - Orientation

Comment

24. Is overly detailed and exhaustive. It would be of benefit to programs and to those who do site visits to have these orientation rules condensed.

Response

The Department has reviewed this comment and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

The current orientation §24.1. as written applies only to OTPs. If an orientation section is needed then it should include discussion of the rules, rights and responsibilities of the OBMAT, and obtaining a signed patient treatment agreement.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

References to dosing, dispensing, or administering should be deleted from §§ 24.3.f., 24.4.a., 24.4.l., 27.2.c.17. and 27.2.d.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

The patient shall receive group and/or individual education in § 24.4., and most of §24 is not applicable to OBMATs and there is much redundancy.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

24.5 Orientation. Again done in OTPs, agreement for treatment along with client handbook covers all these items.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment

Section 25 – Required Services

Comment

25. This section says the biopsychosocial assessment must be completed prior to admission, whereas 19.7.d says it has to be within 30 days of admission. We need clarification as to when this actually must be completed.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

We are not a social services agency which is better suited for the assessments in §25.1.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

The requirements of §25.1 are ideal, but “fully and reasonably available to patients” is not realistic for many areas of West Virginia.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

25.2. It would seem unnecessary that each patient would need to have a full medical examination. This is not needed prior to prescribing psychiatric medications and should not be required for OBMAT. Urine drug screen and a general blood panel as well as evaluation by physician should suffice.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

We recommend this section be carefully aligned with nationally recognized treatment guidelines, such as ASAM’s National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use.ⁱ As written, there are several requirements that are out of step with nationally recognized treatment guidelines. For example, there is no clinical need for patients to have a physical and biopsychosocial assessment every 90 days. These should be conducted initially and then as clinically indicated. Requiring such frequent assessments serves no medical or therapeutic purpose and would surely increase costs to patients. Further, as explained in reference to Section 69-12-33, below, random drug testing is unwarranted and untenable in some cases.

~~25.2. Each OBMAT program shall require every patient to undergo a documented physical assessment by a program physician or a physician extender under the supervision of a program physician, before admission to the OBMAT program. The full medical examination shall be completed at the time of admission and prior to the first dose of medication-assisted treatment medication. The results of serology, toxicology and other tests must be completed within 14 days following admission.~~

25.4. Each patient accepted for treatment at an OBMAT program shall ~~be assessed including physical and~~ undergo a biopsychosocial assessments initially ~~and at least every 90 days following the initial assessment~~ by qualified personnel who shall determine the most appropriate combination of recovery-oriented services and treatment for the patient.

25.6. ~~Random drug testing of all patients shall be conducted during the course of treatment as required in section 33.~~ Each OBMAT program must provide adequate testing or analysis for drugs of abuse in accordance with generally accepted clinical practice.

~~25.10.a. Establish a strong working relationship with several treatment providers offering different levels of treatment;~~

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

The time to conduct a biopsychosocial assessment is contradictory in §§ 25.3. and 28.1. and should be within 30 days.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

25.4 Biopsychosocial q 90 days. Clinical eval at intake and annually.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

25.5 The coordination of care agreement is currently used when the treating physician and treating counselor do not work in the same agency. Within seven days of the admission of a patient, the OBMAT program shall complete a post-admission initial assessment, an initial individualized treatment strategy or plan of care and a coordination of care agreement. A coordination of care agreement is only required when the treating physician and treating counselor work at different agencies/programs.

Response

The Department has reviewed this comment and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

Section 25.5 allows for a treatment strategy or plan of care however throughout the rest of the rule (example 27.2.b) there is no more mention of the treatment strategy in place of the plan of care. In all places where a plan of care is mentioned there should also include the option of a treatment strategy in it's place.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

The rule requires an OBMAT program to provide "adequate vocational, educational" services while these may be needed services for those in recovery, they are not the responsibility of the OBMAT provider to supply these. These are not health services and will probably not be reimbursed by any health payer. We would ask that they be deleted from the rule.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

The coordination of care agreement in Behavioral Health industry is currently used when the treating physician and treating counselor do not work in the same agency. We would suggest this language be changed as follows: 25.5 Within seven days of the admission of a patient, the OBMAT program shall complete a post admission initial assessment, an initial individualized treatment strategy or plan of care and a coordination of care agreement, provided a coordination of care agreement is only required when the treating physician and treating counselor work at different agencies/programs. Section 25.5 allows for a treatment strategy or plan of care however throughout the rest of the rule (example 27.2.b) there is no more mention of the treatment strategy in place of the plan of

care. We recommend the proposed rule be reviewed to ensure that in all places where a plan of care is mentioned that the option of a treatment strategy be included as well.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

Data in §25.7 should be annotated as available in house or through contracted counselors.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

25.7. counselor – level of education of counselor not specified, as previously mentioned in other comments.

Response

The Department has reviewed this comment. Existing provisions in the rule address this issue and, therefore, no changes were made.

Comment

Section 25.10.a. is a good idea, but how would you enforce this? Alternatively you could say "it is suggested that each OBMAT program establish a strong working...."

Response

The Department has reviewed this comment. The proposed change does not meet the intent of the regulation and, therefore, no changes were made.

Comment

25.10.b. Clarify agreement?

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

The requirements of §25.11 are beyond the scope of practice of any office-based treatment program for addictions or for mental health.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made

Section 26 - Counseling

Comment

Counseling

- Transmissions of HIV, Hepatitis. Medicaid won't reimburse.
- Domestic Violence. Medicaid won't reimburse.
- Same sex counselors. Hard to do due to work force issues.
- Counseling times. Inconsistent with Medicaid Regs.
- Counseling staff 1 to every 50 patients. Don't have the professional staffing.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment. Please refer to additional specific comments and responses below.

Comment

There is no scientific evidence to support the frequency of required counseling sessions proposed in this rule, nor is there evidence to support a requirement for monthly individual counseling of patients who have had a positive drug screen. ASAM's National Practice Guideline includes the following recommendation related to psychosocial treatment and treatment with buprenorphine:

Clinicians who are prescribing buprenorphine should consider providing or recommending office-based or community-based psychosocial treatment. There is some research evidence that the addition of psychosocial treatment improves adherence and retention in treatment with buprenorphine; however, these findings are mixed. It is recommended that clinicians offer patients psychosocial treatment early in their treatment with buprenorphine. Effective therapies may include the following:

- (1) cognitive behavioral therapies;
- (2) contingency management;
- (3) relapse prevention; and
- (4) motivational interviewing.

Importantly, no one type or set frequency of psychosocial treatment is recommended for all patients. Instead, a patient's treatment plan – both the medication and the psychosocial treatment – should be individualized to the patient's unique needs. It is counterproductive, costly and contrary to accepted clinical practice to mandate a certain frequency or type of counseling service for all patients. As such, we recommend this section be revised to require physicians to provide, directly or by referral, office-based or community-based psychosocial treatments consistent with the recommendations of accepted national practice guidelines.

~~26.7. The clinical staff caseload ratio as defined in section 7.5.e. shall: [[Delete entire subsection.]]~~

~~26.8. Counseling sessions shall be provided according to generally accepted best practices and shall be offered: Counseling is an integral component of medication assisted treatment. Clinicians must ensure and document that patients receive adequate counseling services, individualized to each patient's needs. [[Delete remainder of subsection.]]~~

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

Counseling should be a part of the process to recovery when using MAT, however the counseling section raises several issues and it should be modified. We would ask the OHFLAC and BMS sit down on the counseling standards and time frames so that the either the rule mirrors the Medicaid framework or Medicaid follows OHFLAC. Both entities are under the umbrella of DHHR and there should be coordination. For example the counseling time frames in 26.8 do not match what BMS will pay for. Also if an OBMAT arranges counseling with a third party at separate location from the OMBAT the Medical Director should not be required to be present during that counseling. Maybe the best solution would be to stipulate the 75% kicks in when OBMAT services that are physical in nature are being performed.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

26.2 Individual plan of care. Needs to be tx strategy or tx plan.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

26.4 counseling matters - would be nice to include co-occurring/dual diagnosis as 26.4.c

Response

The Department has reviewed this comment and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

26.5 Same sex csllrs. For small programs this would be difficult to manage.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

26.7.a. This is a great standard if West Virginia did not have a workforce shortage in this field, the words "to the degree possible based on available staff" should be added.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

26.8.a.-d. The mandated therapy sessions are not feasible for small practices and not clinically indicated. Weekly sessions for the initial six months, biweekly for several months and then monthly have worked well in our practice for many years and resulted in over one hundred patients stable and in maintenance. Mandating the frequency of sessions intrudes onto the doctor-patient relationship and does not allow for individualized treatment plans. It micromanages what we do and how often, even if not clinically indicated.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

26.8 Requiring twice weekly counseling sessions during the first 30 days is a lot. It's asking of our population, who already have a difficult time traveling in once a week for treatment, because each trip in likely includes transportation costs, possible childcare coverage, possible work scheduling issues, etc. You have elsewhere included the language "as clinically indicated," so I would ask for the same respect when we treat our patients during this first 30 days. This ties in to 26.9 as well; when our patients relapse, sometimes we bring them in for additional counseling, sometimes we don't. Making this a mandate takes away the "individualized treatment" that you speak of during 69-12-29 Individualized Treatment Plan of Care.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

26.9. Mandating individual counseling sessions is not feasible for those practices using the group therapy format and is not needed. The pressures coming from the strength of the group are far more effective in

helping patients who have slipped than just meeting one to one with a counselor. Group Therapy has been described as "the definitive treatment for producing character change," and "the treatment of choice for chemical dependency" (Textbook of Substance Abuse Treatment, 2nd Edition, by Marc Galanter MD, page 370).

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

26.12 – is more logical to follow with state insurance requirements, as suggested above.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Section 27 – Provision of Coordination of Patient Care; Post-Admission Assessment and Initial Plan of Care.

Comment

The requirement that all patients undergo an “initial post-admission assessment” appears to duplicate the requirement in §69-12-20 that patients undergo a “pre-admission initial assessment,” as well as the subsequent requirement in §69-12-28 that the program shall complete a physical and biopsychosocial evaluation of each patient within 30 days after admission. The three requirements are redundant (for example, each requires a physical examination (20.3.1, 27.2.c.1, and 28.3.a), a screen for communicable diseases (20.3.k, 27.2.c.7-10, and 28.3.h), and an inquiry to the Controlled Substances Monitoring Program (20.3.h, 27.2.c.11, and 28.3.f), among other things).

These redundant requirements for multiple and frequent assessments are not only not clinically necessary, but would be extremely costly for both the physician and the patient. We recommend these three sections be re-evaluated and streamlined to reflect national practice guideline recommendations for one initial assessment including appropriate medical history, physical examination, and laboratory tests to determine the appropriate course of treatment and individualized treatment plan. Only when clinically indicated should such a comprehensive patient assessment be repeated.

The final rule should also make explicit that all physical examinations and laboratory testing can be completed by a separate primary care provider for patients of those practices, such as psychiatric practices, that don’t have primary care services onsite.

~~27.2. Initial Post Admission Assessments. [[Delete entire subsection.]]~~

~~27.3.a.1. Follow up physical examinations, by a program physician or a supervised physician extender;~~

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

27.2.c.18. Did you really suggest that our patients’ assessments include x-rays and a pap smear?

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

27.2 Is this different from the psychosocial assessments or treatment plans or physician assessment? The way it currently is written now there would be two within 7 days.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

27.2.b. Plan of care within 7 days. This is for coordinated care need to state tx plan or tx strategy.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

27.2.c.7 & 27.2.c.8 The initial post assessment requires a tuberculosis and syphilis screening. These are tests not often medically necessary or regularly performed by medical personnel during MAT induction. Remove the requirement for tuberculosis and syphilis screenings as part of the post admission assessment.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

27.2.c.7-27.2.c.11 Required medical testing. If going to be required referred out to PCP or health dept?

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

References to dosing, dispensing, or administering should be deleted from §§ 24.3.f., 24.4.a., 24.4.1., 27.2.c.17. and 27.2.d.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

27.2.d. Requirement for physical examinations same day as prescription of MAT. Current recommended agency protocol is for physical exam. And lab results to be available to prescribing physician to review for day medication is inducted. Having results on hand seems to be more safe.

Response

The Department has reviewed this comment and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

27.2.f.3. W/in 27 days. If client does not comply with then are we required to d/c/?

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

27.3.a.1. f/up physicals. Clarify actually physical exam as like a GP or to evaluate for stability in MAT?

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made

Comment

27.4 Initial plan of care. Again tx strategies are used for clients that do not need coordinated care.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

27.10 Tx. Plans. Take home medications. Tx plans or treatment strategy.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Section 28 – Comprehensive Physical and Biopsychosocial Evaluations

Comment

This section is redundant; includes language about physical exams, which are not warranted in OBMAT program, as noted above; and the 30-day time frame conflicts with earlier sections of the rule. We recommend that the section should be deleted in its entirety.

~~§69-12-28. Comprehensive Physical and Biopsychosocial Evaluations.~~ [[Delete entire section]]

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

28. Physicals. I don't know that any client's insurance is going to approve and cover a physical that occurs at 30 days and then every 90 days thereafter if you are meaning a full physical, clarify?

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

28.1. This subsection seems inconsistent with current code as well as another section of this rule. While this subsection requires a biopsychosocial exam within 30 days after admission, §16-5Y(m)(5) states: "An alcohol and drug abuse counselor, an advanced alcohol and drug abuse counselor or other qualified counselor, psychiatrist, psychologist or social worker shall perform a biopsychosocial assessment, including, but not limited to, a mental status examination of a patient on the same day or no more than seven days prior to the day that the physician initially prescribes, dispenses or administers a medication-assisted treatment medication . . ." and section 25.3 of this OBMAT rule states: "Each OBMAT program shall require every patient to undergo a complete, fully documented biopsychosocial assessment by a program counselor before admission to the OBMAT program. The full biopsychosocial assessment shall be completed at the time of admission and prior to the first dose of medication-assisted treatment medication." Were one to follow the relaxed time period in 28.1, one would be in violation of the underlying statute. Regardless of the timeline that is proposed by the agency rule, clarity and consistency as to when the initial biopsychosocial examination should take place is warranted.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

Superfluous words “or, if an OBMAT program” should be deleted from §28.1.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

28.2.d. Other appropriate and permitted collateral sources. Not sure what this is?

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

28.3.h. These tests can be performed by the patient’s family physician or health care clinic as needed and are beyond the scope of a small psychological/psychiatric practice.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Section 29 – Individualized Treatment Plan of Care

Comment

We recommend that patients who choose medically-supervised withdrawal be required to sign a consent form, to be included with their patient records, indicating they have been informed of the estimated risks of subsequent relapse, including the increased risk for death, as compared to treatment with opioid agonists.

29.1. Delivery of patient care and treatment interventions shall be based on the needs identified in the individualized treatment plan of care, which can be embedded in clinical notes.

29.8.a. OBMAT programs shall make every effort to retain patients in treatment as long as clinically appropriate and medically necessary in accordance with approved national guidelines and acceptable to the patient and compliant with the treatment agreement.

~~29.8.b. At the time of the quarterly review, the patient shall again be presented with the option of participating in alternative treatment, such as medically supervised withdrawal. The patient shall sign and date a statement indicating whether he or she wishes to participate in an alternative form of treatment or remain within the program in an ongoing recovery-oriented maintenance format. The statement shall be included with the patient’s individualized treatment plan of care.~~

29.8.c. If the patient chooses the option of participating in alternative treatment, ~~the individualized treatment plan of care shall include a consent form signed by the patient acknowledging that under the detoxification protocol the strength of maintenance doses of medication-assisted treatment medication should decrease over time and that the participant is required to work toward a recovery-oriented lifestyle~~ this should be documented in the clinical notes.

~~29.10. Coordination of Care Agreement. [[Delete entire subsection.]]~~

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

29. Requirement for comprehensive treatment plan and review every 90 days. Consumers in low-end outpatient programs are not required to have a treatment plan, and 90 day reviews are not reimbursed generally. Allow BHCs to continue to adhere to Medicaid requirements.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

Individualized Treatment Plan of Care in §29 is OTP language; to make it salient for OBMATs we need to include a statement that the plan of care can be a separate document or embedded in the clinic notes as part of ongoing patient care. An exception is §29.4. which does have some application to OBMATs. An ideal ITPC would be updated on a more frequent basis early in treatment to reflect the patient's progress and challenges.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

The provisions of §29.5. are beyond the scope of practice for an OBMAT.

Response

The Department has reviewed this comment and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

Vocational evaluation and financial stability in §§ 29.5.h. and 29.5.f. are outside the scope of a physicians' practice.

Response

The Department has reviewed this comment and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

29.7. We are in complete agreement that family involvement can be an important part of the treatment process and the opportunity for such should indeed be provided if appropriate. However, sometimes one's own family member/s do not represent the positive support system that is desirable in therapy and can retard the progress otherwise being made with the patient. Sometimes, family members may be part of a similar culture which has produced the patient suffering from addiction. In other circumstances, "each patient" as provided for in the agency proposed rule, may not have family available for purposes of being involved. Therefore, we request that language be added to this subsection which provides flexibility for such circumstances. A modification in the language used in 29.7 could easily accommodate this circumstance by simply beginning the section with the words "Where appropriate" prior to the word "Each" at the start of the sentence in 29.7.

Response

The Department has reviewed this comment and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

The word “provider” should be substituted for “medical staff” in §§ 29.8. and 32.1. since it is the provider who makes treatment decisions.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

29.8b - This is OTP language not appropriate for OBMAT.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

If §29.8.a. stays in, the words “and acceptable to the patient and compliant with the treatment agreement” must be added to the end of the statement

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

29.8.d. Thank you for including this. Not everyone “gets” the importance of that.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

29.8.f. Re-entry in good standing. This would also need to consider that there would be a pending in the program at the time the client wished to do so or referral would be needed.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

29.10.a. This is only necessary when these staff persons are NOT employees of the same company. We would recommend 29.10.a. The coordination of care agreement shall be signed by the patient, program physician and primary counselor when the primary physician and counselor are not employed by the same company. If a change of program physician or primary counselor takes place, a new agreement must be signed.

Response

The Department has reviewed this comment and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Comment

29.10.c.5. Medications and dosage. As this can change we would have to sign a new one more than annually, this is typically documented in the chart.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

29.10.d. Coordination of care agreement. Currently is one we use from Medicaid.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Section 30 – Detoxification Program

Comment

Detoxification Programs

- Short and Long Term. Should be able to link to the service, if needed.
- Program physician provides on-site supervision and oversight. We have to offer these?
- Maintenance treatment. Should be voluntary.
- Detox prior to incarceration. Difficult to determine.
- Take home meds. More for Methadone.
- Maintenance treatment. Medical necessity issue.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment. Please refer to additional specific comments and responses below.

Comment

30. Much of this section seems to apply to methadone treatment (Discussion of unsupervised and take home doses) and has no place in this ruling. There is no evidence suggesting that maintenance treatment should be discontinued in a set period of time, yet the ruling suggests it should be done in two years. The patient should be maintained on the lowest EFFECTIVE dose. Therefore, there should be no need for a provider to explain why they are still on medication past two years. However, it is reasonable to expect that there has been an attempt on the part of the treatment team to wean to the lowest effective dose for that individual. It is not unusual for cash-only clinics to put a patient on a high dose on admission and never try to decrease the dosage. I agree that this needs to change, but expecting everyone to be off in two years is not the answer. It may be useful for an explanation to be required if the patient is still on the same exact dosage after the initial two years of treatment.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

30. It seems that the words detox and withdrawal are being used interchangeably, but they are not the same.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

A receiving facility for detox in §30.1. should assume full care and release the OBMAT from documentation

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

30.1. Cooperative Agreements. As they arise or prior to situation presenting itself? Typically in OTP they would bring them to dose, but OBMAT is a rx is the prison going to fill the rx for them?

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

30.3. This could cause conflictive demands on OBMAT programs where a program is required under other provisions of the rule to accept patients transferring from another program. Language should be modified in this subsection to clarify how the impact of two or more detoxification episodes would affect patients transferring from one OBMAT program to another.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

30.9.e. eliminate word “methadone”

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

30.11.b. Take homes. This is OTP language not OBMAT.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

The following sections are not relevant to OBMATs and should be deleted: 30.11.b., 30.12.b., and 30.12.c.1-4.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

I suggest continuing detoxification care in §30 be offered by referral, rather than by the program itself, and §§ 30.11, 30.12.c. are for methadone, not buprenorphine, programs.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

Dosing programs or take-homes in §§ 8.1.c.2., 30.11.b., and 33.3.c. don’t apply to OBMATs.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

30.13.c.. Amt. of sessions. Seems more OTP than OBMAT.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

Offering three counseling sessions a week in §30.13.c. is unrealistic without enormous staffing levels and great expense.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

30.14. 2 years then detox unless doc continues. Earlier in this document it states that as long in compliance client can stay indefinitely must clarify which way it is going to be this document states both.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

Discontinuing maintenance treatment within two continuous years after treatment is begun in §30.14. is not indicated for many patients and should be removed from the rule.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Section 31 – Administrative Withdrawal

Comment

The other things listed in §31 really reflect OTP but are applicable to OBMAT also.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

31.4.b – include violating peer confidentiality

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made

Comment

Section 31.4.c. is directed at the wrong agencies and pointless.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

Administrative withdrawal in §31.4.d. primarily occurs because the patient has broken the treatment agreement.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

31.6. female patients – this assumes compliance. (Suggestion: It should say something along the lines of “if female patients who have a positive pregnancy test are noncompliant with treatment and/or continue to relapse/engage in poly-substance use then they may be discharged if the primary treatment team determine they can no longer provide safe provision of medication, when considering risks and consequences.)

Response

The Department has reviewed this comment and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Section 32 – Medical Withdrawal**Comment**

Section 32 should be eliminated.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

32.4 There is no need to perform a new complete biopsychosocial assessment on a patient who is readmitted within 30 days. It would also not be likely that an insurance company would want to reimburse for a second such assessment within a month.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

Change the word “dose” to “last prescription given” in §32.5

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

Drug blood levels in §33.2.b. are unnecessary, as are observed urine screens in §33.2.d.3. While alcohol testing in §32.2.g. is a good idea, it is not relevant prior to dosing in an OBMAT.

Response

The Department has reviewed this comment and no changes were made in response. The rule provision is consistent with the requirements of the statute.

Section 33 – Laboratory Services; Drug Screens**Comment**

Laboratory Services – if positive screens, increased counseling. Workforce issues.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

There is no evidence to support the requirement that patients undergo monthly random drug testing. The ASAM National Practice Guideline notes that there is little research on the optimal frequency of testing, and that patients participating in office-based treatment with buprenorphine may be tested at each office

visit. Requiring additional random drug testing outside a patient's routine monthly visit is both costly and not clinically indicated.

Additionally, requiring use of federally certified laboratories is not clinically necessary and is costly for patients. Qualitative tests using dipstick technology are generally sufficient for clinical purposes. The ASAM National Practice Guideline recommends testing should be done for buprenorphine, substances such as heroin and marijuana, and prescription medications including benzodiazepines, prescription opioids, and amphetamines. However, it does not call for quantitative testing and does not call for determining the type of benzodiazepine present (as 33.2.e.4 requires); qualitative testing for the presence or absence of these substances is sufficient to understand whether a course of treatment is working for a patient or inform adjustments to the patient's treatment plan.

Further, it is not necessary to require observation for every drug test, particularly for stable patients. There are generally other indicators that will alert a treatment provider to a problem with the patient apart from directly observing a urine drug test. Moreover, this requirement is not feasible for small practices, who may have to hire additional staff, and can negatively impact a physician-patient relationship. We recommend this requirement be struck from the final rule.

Finally, the proposed requirements for weekly counseling and weekly treatment meetings following positive drug screens are not supported by any clinical guidelines or scientific evidence base. The proposed rule is also unclear as to the duration that these weekly sessions would be required. The requirement that patients be discharged from treatment or offered detoxification and then discharged following a fourth positive drug screen is punitive and not therapeutic. Such a requirement runs counter to the scientific understanding of addiction as a chronic disease that often involves cycles of relapse and remission. Episodes of relapse are not an indication that treatment should be terminated; instead, relapses should lead to a re-evaluation of the treatment plan and possible adjustment of medication dosage. We recommend this section (33.3) be struck in its entirety and be replaced with a simple requirement to document a re-evaluation of the patient's individualized treatment plan after each positive drug screen.

33.1. All patients in the OBMAT program shall undergo monthly drug testing during the first year of recovery. ~~Random drug testing of all patients shall be conducted during the course of treatment as required in section 33.~~

33.2.a. OBMAT programs shall ~~work carefully with toxicology laboratories to ensure valid, appropriate results of toxicological screens. Workplace testing standards are not appropriate for urine testing. Testing shall be done only by~~ send samples to laboratories with appropriate federal certification when necessary and clinically indicated.

~~33.2.d.1. A patient receiving medication assisted treatment medication maintenance services must at least one random drug screen per month during the first year of treatment and random drug screens quarterly thereafter.~~

~~33.2.d.3. When using urine as a screening mechanism, all patient drug testing shall be observed to minimize the chance of adulterating or substituting another individual's urine.~~

33.2.e.1. Buprenorphine, ~~especially in~~ and frequently the ratio of ~~to~~ Norbuprenorphine/buprenorphine;

33.2.e.4. Benzodiazepines, ~~including testing procedures that detect diazepam, clonazepam, alprazolam and lorazepam;~~

33.3.b. A positive drug test result after the first six months in an OBMAT program shall result in the following a reevaluation of the patient's individualized treatment plan. [[Delete remainder of subsection.]]

33.3.c. Positive screens for tetrahydrocannabinol, delta-9-tetrahydrocannabinol, dronabinol or similar substances shall be carefully clinically evaluated ~~and shall in most cases result in reduction in take home medication privileges unless other action is considered appropriate by the medical director or program physician and primary counselor.~~ Testing positive solely for ~~tetrahydrocannabinol, delta 9 tetrahydrocannabinol, dronabinol or similar substances~~ any illicit drugs shall not serve as a basis for discharge from the program. Each OBMAT shall develop policies and practices based on sound clinical judgment and individualized for each particular patient.

33.3.e. Special precautions shall be taken when a patient has both sedatives and buprenorphine in their urine. This requires immediate discussion with the patient about the dangers and shall be noted in the patients' record.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

33.2.a. Outside labs only. CLIA waved facilities staff have training on ding dip tests and send out any positives for confirmation all would not need set out. In cases where the client admits to use on positive dip there is no reason to send out.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

33.2.d.3. Routine observation of urine collection is not indicated or necessary. It is necessary in suspected instances on a case by case basis only and when clinically indicated, not just routinely. Additional staff would be needed to be able to accomplish this administrative task, which would increase the cost to patients.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

Buprenorphine and frequently the ratio of norbuprenorphine/buprenorphine should be included in §33.2.e.1.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

33.2.e.5. Cocaine or metabolites of same

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

33.2.e.7. Tetrahydrocannabinol, delta-9-tetrahydrocannabinol, dronabinol or other similar substances or metabolites of same

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

The last two sentences in §33.2.g. should be deleted as not relevant to an OBMAT.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

There needs to be a subsection under §33.3 that notes special precautions to be taken when a patient has both sedatives and buprenorphine in their urine requiring immediate discussion with the patient about the dangers and must be noted in the patients record.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

33.3.b. additional therapy for positive UDS – there is no time frame specified. How long must clients be receiving this minimum of counseling? 1 month? Until a negative UDS occurs? Until treatment team say okay?

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

The internal section reference in §33.3.b.1. should be corrected from 26.5 to 26.9.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

33.3.b.4. State 4th illicit d/c. Still have ability to be more stringent, 3 versus 4.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

33.3.b.4. Guidelines for dealing with continued illicit drug use by clients in program. FMRS currently follows SAMHSA and Medicaid guidelines for continued use of illicit drugs by MAT patients. BHCs should follow Medicaid guidelines.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

The first sentence in §33.3.c. should end after the word “evaluated” and the rest of the sentence stricken.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Section 34 – Special Populations

Comment

The burden for establishing agreements and coordination between medical practices and the criminal justice system should fall on the criminal justice system, which should be required to allow patients with opioid addiction to be treated with agonist or partial-agonist medications as clinically indicated. The court system and probation officers should be encouraged to work with the state’s medical community to ensure justice-involved individuals with opioid addiction are able to access evidence-based care.

Further, while we fully support new legislation that requires pregnant women to receive priority for treatment opportunities, OBMAT providers cannot be expected to provide instruction on prenatal medical care, and patients should rely on their obstetricians for advice on prenatal care.

34.2.c. Each OBMAT program shall establish linkages with licensed behavioral health providers in the community or in the program’s facility.

34.5.a. Pregnant women seeking and needing treatment shall be enrolled in the OBMAT program and provided treatment in accordance with guidelines and protocols from approved authorities. They shall be given priority in accordance with applicable state law.

34.5.b The OBMAT program shall ensure ~~that appropriate referrals for every pregnant patient who does not have an obstetrical provider. has the opportunity for prenatal care, either onsite or by referral.~~ Care for the pregnant patient with an opioid use disorder should be co-managed by the OBMAT program and the patient’s obstetrical provider. ~~If the arrangement is by referral, the~~ The OBMAT program shall have agreements in place with the patient’s obstetrical provider; including informed consent procedures, which ensure exchange of pertinent clinical information regarding compliance with the recommended plan of medical care.

~~34.5.c. If not available elsewhere, the program shall offer basic instruction on OBMAT maternal, physical and dietary care as part of its counseling services and document the provision of the services in the clinical record.~~

~~34.5.d. With respect to pharmacotherapy for opioid addicted pregnant women in medication-assisted therapy, the program shall ensure that: [[Delete entire subsection.]]~~

~~34.5.d.4. If a pregnant patient elects to withdraw from medication-assisted treatment, that withdrawal is not initiated by the program before 14 weeks and after 32 weeks gestation; perform regular fetal assessments as appropriate for fetal age and require that withdrawal is supervised by a physician experienced in substance use disorder medicine.~~

~~34.5.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 training. Any referral shall be documented in the patient’s record.~~

~~34.6.a. Each OBMAT program shall establish agreements and develop and implement procedures to coordinate with agents of the criminal justice system on behalf of patients insofar as permitted by patient confidentiality requirements.~~

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

34.1.b. cocaine should not be specifically listed. More appropriately, it should read “alcohol, illicit drug use, and other drug abuse”. However, this is redundant, because previously it reads that staff must be appropriately trained.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

Add the words “or in their office” to §34.2.c.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

34.2.d. Uses tx plans language. Needs tx strategy clarified if on both or only tx plans.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

34.4.b. MAT and pain management. If the client is prescribed and opiate in their pain management clinic current they would not be appropriate to place in MAT.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

The services in § 34.5. are beyond the scope of practice for an OBMAT.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

Should there be language in 34.5. that pregnant women should be given priority into OBMAT treatment? I am pretty certain that we just passed a law to that effect. See §34.5.c. for OBMAT maternal physical and dietary care.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

On-site parenting classes in §34.5.g. goes beyond the scope of treating addiction; likewise for the reproductive health issues of §35.5.h.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

34.6.a. The criminal justice system has not and will not cooperate with patients on buprenorphine. The Court Clinic system and state probation officers refuse to allow patients to take buprenorphine while in treatment.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

The requirement of §34.5.d.4. is never indicated and should be discouraged. However, if an OBMAT patient insists, it must be done on an inpatient service with close monitoring

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Section 36 – Licensure and Registration Denials, Revocations and Suspensions**Comment**

36.2.d. Drugs on premises. Our program is by prescription no medication for MAT is kept on premises.

Response

The Department has reviewed this comment and no changes were made in response. The rule provision is consistent with the requirements of the statute.

General Comments:**Comment**

Physicians prescribing under a DATA 2000 waiver in an office-based setting usually do not operate a stand-alone addiction-only facility. These cumbersome and difficult to manage regulations will result in a reduction of physicians prescribing Buprenorphine in office-based settings in addition to the provider's primary specialty.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

Any testing for lab work must meet medical necessity to be billed to insurance or else it is a violation of the federal False Claims Act. A statistically valid sample or lottery selection of patients does not meet the "medical necessity" for each patient.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

The recent federal increase of the buprenorphine patient limit from 100 to 275 per practitioner makes the need for clear, simple, useful rules more imperative. The rules should not be so cumbersome as to turn away willing and qualified physicians.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

The proposed rule fails to take into account that many OBMATs operate within their primary or specialty practice. The federal government encouraged primary care doctors to offer buprenorphine as a way to reduce addiction, and your regulations will have a chilling effect and are far beyond the intent of SB 454. The patient-to-doctor ratio has just been increased by the federal government, but West Virginia appears intent on shutting down access. The rules are cumbersome and tedious, and will decrease time with the patients while doctors do paperwork. Most doctors won't bother and abandon their patients instead. 2.1 Provide a definition for MAT instead of incorporating by reference.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

The proposed regulations are overly cumbersome and seriously jeopardize patient treatment. Requiring meaningless tasks does nothing to improve quality of care and will reduce provider/patient time. This law also stereotypes opioid use disorder.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

Why are you limiting treatment to two years when SAMHSA states that it may be indefinite based on medical necessity? These regulations will reduce the number of addiction services.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

Our 250 patients will be at risk if this bill passes in its current form. I am embarrassed and disgusted by this proposal. We have recognized the opioid epidemic and are trying to increase access to care. The majority of MAT programs will not be able to keep up with all the regulations. Some oversight would be a good thing. Not all practitioners get into this work for the right reasons. We need to do something about the pill mills and cash clinics. Comprehensive care, access to therapy, random UDS and pill counts should be part of the proposal. But 69-12 goes too far with 66 pages of regulation, documentation, and fees with additional manpower/cost to implement. This will close the bad clinics but make it impossible for the good ones to keep running. Access to care will be even more difficult than before DATA 2000. We have a multi-sheet waiting list of people desperate to get into our program.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

Important general comment: the rule regularly refers to days or hours of operation for the OBMAT program. This is clear when the clinic exists only to provide mat services. However, in many cases (as with community mental health centers), the clinics operate to provide a variety of services, only one of which is OBMAT. In these cases, the rule needs to clearly indicate the rule only applies to the clinic when it is delivering OBMAT services.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

The rule throughout requires continued assessments and plans of care being completed every 90 days or more frequently. Currently Medicaid only reimburses for these assessment and planning services at this frequency for "coordinated care" services which MAT currently is not. Discuss with Medicaid the inclusion of MAT services as a "coordinated care" level service or reduce the frequency of assessment and planning services required to the "focus care" level (once per year).

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

The law and this Rule go against the philosophy of the federal government's DATA 2000 statute, which established office-based treatment of opioid addiction using buprenorphine. It was designed simply to treat outpatients in an office environment. It is administered by the Substance Abuse and Mental Health Services Administration (SAMHSA) and oversight is provided by the Drug Enforcement Administration (DEA), who have in fact audited our practice twice and found no deficiencies. The Governor's Bill and particularly this Proposed Rule do not carry forward this philosophy. Private medical practices do not run programs. They treat patients. The Rule is written as if private physician offices employ multiple staff members to fulfill roles such as administrator and community relations coordinator. Ironically, this West Virginia law, which will greatly reduce the number of physicians willing to jump through all the hoops to comply, comes at a time when the federal government, recognizing the need to be able to treat more patients, has just increased the maximum number of patients that a specially certified physician (either in Addiction Psychiatry or Addiction Medicine) from 100 to 275 patients.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

The law and the Rule do not adequately address the capabilities of psychiatrists, who are able to provide office-based treatment for patients under DATA 2000 by themselves with only a secretary, since they can provide any psychotherapy or counseling needed. That standard should also apply under this Rule.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

Many parts of the Proposed Rule will greatly increase costs to patients with little or no clinical indication or benefit. Examples are administrative need for a biopsychosocial assessment and a physical examination every 90 days, need for a quantitative urine drug screen from a certified laboratory when dipstick qualitative technology is accurate, convenient, clinically appropriate and sufficient. Certified laboratory tests cost more than \$100 each. Many of our patients have no health insurance and cannot afford this added needless expense. Additionally, the Proposed Rule utilizes terms and definitions related to Methadone clinics rather than an office-based practice, such as "take home medications", "administered medication", and "interagency agreements", which have no meaning for an office practice.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

In our opinion, if parts of the Proposed Rules are implemented, it will force me to close my practice. I suspect this will result in other practitioners ceasing to provide needed services, which will result in hundreds of individuals not getting treatment for their addictions. I fear that many will return to abusing illicit drugs, with concomitant fatalities.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

Rules applying to licensing and reviews of OBMAT Programs. Licensed BHCs should not have to have additional licenses or reviews other than Medicaid and OHFLAC. Current licenses/reviews for BHCs should be sufficient.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

I am in favor of suboxone treatment; however, strict, intimidating guidelines will consequently make opioid addiction problems worse. Forcing clinics to accept Medicaid may make smaller, privately run clinics close. Large clinics may be understaffed leading to compromised time spent with patients, contrary to good medical care and could lead to pill mills. I agree with having a Medical Director, but do not agree with the requirement of an advanced degree or training. I propose the new federal limit of 275 patients instead of 100, but without further guidelines or restrictions. However, we do need rules to protect physicians from retaliatory actions from patients.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

These rules would have a devastating impact on small, rural practices like my own in Chapmanville, especially those with a large number of Medicaid patients. I have reached full capacity under current guidelines and have a waiting list of 200. I am very concerned about the feasibility of continuing while absorbing additional financial burdens. Also, many of these regulations are not appropriate for OBMATs, but methadone clinics instead. Many patients will not have access to care if rural clinics are forced to close. We would need at least three additional employees who are difficult to find with the required educational background in §7.2.a. Either the medical director or registered nurse with substance abuse experience can perform these duties.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

The registration and renewal fees are exorbitant, and should be every other year, not annual.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

We have three locations serving 250 patients who we see individually. If 69-12 passes in its current form, we will be forced to close.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

After carefully reviewing the proposed rules, I have come to the conclusion that it is too complex for my solo practice, which focus only on Suboxone Treatment, to continue operation.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

My recommendation is restrictions on clinics that are predominately/only cash-pay.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

My recommendation is guidance on the amount of drug prescribed and not to titrate the patient down.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

My recommendation is full scope review and employment and housing options for patients. Belgium and Portugal have some innovative approaches.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

My recommendation is enhanced support and workforce training services.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

My recommendation is utilize research and evidence based tactics to address addiction. Essentially, asking, "has that been successful before?" when a recommendation has been proposed.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

As a psychiatrist, I see a large number of patients struggle with opiate addiction. The proposed regulation for Medicated-assisted Treatment of opiate dependence adds requirements that are not absolutely necessary, making it much harder for Suboxone Clinics to operate. Opiate addiction is an epidemic. It is

already hard for patients to get in a Suboxone program and the proposal is going to make it even harder, limiting access to this life saving treatment.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

I am a board certified psychiatrist providing MAT to patients with opioid addiction in Wheeling, WV and Morgantown, WV. I write to voice my concerns regarding rule 69-12 in its current form. I must first say that I applaud the effort on the part of the state to eliminate the handful of very poor quality MAT clinics which exploit patients with addiction for financial gain with little regard to quality of treatment and impact on community. These programs give MAT a bad name and threaten to turn public opinion against this incredibly valuable weapon in the fight against opioid related overdose deaths. With that said, I believe that this could be accomplished with a few simple rules. Should this rule take effect in its current form, I fear that many providers will be unable to continue providing this life saving treatment. This comes at a time when limited access to treatment is already contributing to the deaths of West Virginians on a regular basis. I know that my own provision of MAT would cease, should this regulation take effect in its present form.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

I believe that, for the most part, the specific changes put forth in their revision of the proposed rule would make it more workable, though I still believe that many providers will find the length of the document and complexity of the language intimidating. There is great fear in the medical community in West Virginia around the prescribing of controlled substances, particularly buprenorphine, and, as such, many physicians may deem it too risky to engage in a practice governed by such a complex rule for fear of accidental failure to comply and any associated penalties or professional sanctions. This perception in and of itself may be dangerous, as we may lose sorely needed providers and fail to recruit new ones on the basis of a rule that may be reasonable in and of itself, but appear intimidating. To summarize, I support efforts to ensure that treatment be therapeutic and never exploitative. I also feel that it is critical that every effort be made to ensure that any regulation is clear and simple and that the utmost priority be given to increasing access to MAT, a lifesaving treatment.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

My concern is payment for the services by the individuals who are needing the treatment. Usually, by the time the Consumer/Patient/Client seeks treatment they are "per-se" at the bottom of the financial ladder (i.e. divorces, no contact with family, living on the streets, homeless, no job, no place to live, no one to help them, owe 'back pay' in child support, jail and court fines, school loans or even overdose/medical bills on top of all the other expenses and their mental issues). The C/P/C could even be a "fine-upstanding citizen" but due to medical problems that may have helped to cause the addiction. The burden to pay for the services even though they may be willing to pay for them could be too overwhelming for the Consumer/Patient/Client and could cause the C/P/C to relapse. I would like to recommend some type of support system (financial or grants) for when the C/P/C starts the system/program and when they are finished. Yes, I understand Medicaid will pay for some of the services and supposedly, commercial or TPA insurances, but those people who do not have insurance and, presumably,

some of them will not qualify for Medicaid services could cause undue financial stress on the C/P/C causing them to possibly relapse. Please recommend to the state of West Virginia to 'come up' with some type of funding to get the C/P/C the financial help they may need to complete the MATP program and enable them to become productive members of our society (again) including working with WV Workforce and WV Dept. of Rehabilitation or any other program that the government may be able to offer. Suggestions for funding: work programs, volunteering in society, cleaning up parks/river streams, helping with the flood victims, hospital volunteering, picking up trash, emptying trash cans, sweeping sidewalks, cleaning cemetery grave markers or other types of programs.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

If the intention of this new regulation is to assure that each patient who is fully compliant with the requirements imposed by the regulation and who is enrolled in an OBMAT program receiving care will receive a full range of useful services, it has done a good job of defining what that means.

If the intention is to increase access to adequate MAT in our region or state, or to make it easier for medical providers to provide this care, it will have the opposite result. This law will discourage a great many physicians from even trying to treat patients with substance abuse. It makes it essentially impossible for any small clinic to provide this care. If this is the intention of the law, fine, but if not, there should be a section in the regulation describing how that is to be accomplished. By restricting access to pill-mill dispensing of prescribed opiates (altogether a good thing), addicted patients were driven to the use of illicit opioids (e.g., heroin). This same "unintended consequence" is likely to occur when access to Suboxone/buprenorphine becomes more restricted.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

Most of the SB 454 document focuses on larger ("licensed") programs with little attention given for smaller clinics trying to assist in providing this care. There is no discussion in the document of requiring the larger clinics to provide support (psychiatric support, counselling support, etc.) to smaller clinics.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

There is no mention in the law about the XDEA limit on the number of patients seen by a single provider as is proposed in the Comprehensive Addiction and Recovery Act (CARA). However, CARA suggests that providers with expanded BUP numbers (275/physician) must be either medical specialists in psychiatry or addiction medicine or work in a "licensed" MAT program (presumably a WV-described OBMAT program), this basically cuts off any possibility of the CARA accomplishing very much in WV.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

Patients may (usually) need life-long MAT maintenance therapy. The law does not address how this is handled.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

The proposed regulation gives very little attention to 12-step programs such as NA or AA or similar programs.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

The definitions and roles in therapy of ancillary or adjunctive therapies are either not addressed or not clearly defined. While MAT must remain the cornerstone for therapy of addiction to opioids, some of these other treatment modalities are very popular and sometimes useful. Who pays for them? How do they fit into the MAT programs?

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

The complicated interface between pain management and substance abuse treatment needs to be addressed.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

Much of the proposed regulation appears to be written with WV Medicaid in mind with somewhat less consideration given to coverage by private insurance carriers.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

Not specifically mentioning the role of the three forms of MAT might be addressed. These are three very different medications with different indications:

- Methadone (only provided in OTP clinics)
- Buprenorphine (including mono-product and combined with naloxone)
- Vivitrol (not a narcotic; not a controlled drug; no DATA-2000 limit on the number of patients who can receive the medication)

(n.b., Does this regulation cover Vivitrol under the same requirements as for buprenorphine?)

(n.b., A number of clinics now use buprenorphine or methadone and even Vivitrol to treat patients. Would such a clinic under this regulation be treated as an OTP or an OBMAT?)

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

Since OHFLAC is given the responsibility of oversight of all OBMAT program, it would be important to define OBMAT somewhere.

- For instance, does this regulation apply to all clinics treating patients with MAT, regardless of payment procedures?
- Does it include clinics only prescribing Vivitrol (a non-narcotic, but still MAT)?
- Is a solo-provider's office treating patients with BUP an OBMAT? Is he not allowed (in the context of this regulation) to treat addiction with BUP unless s/he declares his practice to be an OBMAT? (Is this requirement in conflict with DEA/FDA regulations and state medical licensure?) (n.b., OBMAT is not found anywhere on the SAMHSA web site. A Google (OBMAT opioid) found only 22 hits, most of which were not relevant and of those that were, many were expressing concerns that the new DHHR rules will seriously compromise the ability of small/solo/rural MAT-providers to continue to provide services.)

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

I have reviewed the office based guidelines proposed for Medication Assisted Treatment (MAT) programs. The proposed rules look like an attempt to make clinics that treat with buprenorphine follow the same rules as those that dispense methadone in daily doses. They are totally different. Using federal regulations written for Methadone clinics will be impossible for an office based physician operating a MAT program to comply with. Please review the proposed regulations to help providers offer their services that are so badly needed to help those in desperate need of addiction treatment. The last thing the State of West Virginia needs to lose with the Drug epidemic are addiction treatment services.

Response

The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made.

Comment

I would like to offer my suggestions regarding the Rules of SB454 regarding office-based medication-assisted treatment. I am currently a therapist in the field of addictions and have been so for the last 22 years. I have worked in MAT with Buprenorphine for the last 10 years. Below I offer my insights and thoughts about the current proposed legislation with two concerns in mind. I believe the primary goals for West Virginia, which are also professional goals of mine, are to 1) increase access to MAT, 2) decrease abuse, diversion and irresponsible prescribing practices. These goals are at times can appear to be in conflict. As I see it, this legislation strives to strike a balance between the two which is not always easy, but necessary, to make MAT a successful intervention in our state.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

The proposed regulations for OBMAT set forth registration, reporting, and other requirements that far exceed the current Federal requirements for Opioid Treatment Programs (OTPs). OTPs, under Federal rules, are not subject to patient limits (as OBMAT providers will be), and are authorized to dispense methadone, a Schedule II controlled substance. The Federal Government has recently finalized regulations for OBMAT providers who are interested in treating between 100 and 275 patients. The new rule, effective August 8, 2016, will require applications to the Federal Government, who can approve, deny, not renew, or revoke the approval at any time. In addition, these OBMAT providers must agree to connect patients to certain services, and are subject to annual reporting requirements. These new rules are

intended to provide accountability, help reduce diversion, and help ensure that patients receive adequate care. West Virginia may want to consider a similar, staggered approach, so that physicians who treat very few patients in rural and other settings are not dissuaded due to burdensome requirements. For example, the rules could stipulate that they only apply to practices with more than 30 patients. Programs with 30-100 patients could be subject to lower fees and less stringent requirements, or be exempt from some requirements. All programs, regardless of size, are required to abide by federal regulations.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

The WV OBMAT regulations could also include conditions under which physicians could obtain a waiver from the requirements, as the WV Legislature approved in SB 454, §16-5Y-6(d). We propose that physicians meeting one or more of the criteria below be eligible for a waiver from these requirements.

Response

The Department has reviewed these comments. Existing provisions in the rule address this issue and, therefore, no changes were made.

Comment

The proposed requirement that every physician practice offering medication-assisted treatment employ a separate program administrator would be prohibitively costly for most physicians. We believe these staffing requirements are far too onerous and should be eliminated in the final rule. Moreover, the proposed requirements related to the program administrator's education and experience are too prescriptive and would severely limit the applicant pool if this requirement for a separate program administrator is retained in the final rule. Many physicians employ only an office manager who may or may not have a bachelor's degree and likely would not have the amount of specialized experience detailed in the proposed rule. We believe this requirement would be too difficult for most physician practices to meet and would be an unnecessary barrier to care.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.

Comment

It would be almost impossible for the smallest programs to completely follow the rules. Most of us believe that these should be able to obtain a waiver to continue to treat patients as per the Comprehensive Addiction and Recovery Act but with special allowances. Having experience in such a setting, I do not believe that a solo practitioner with limited resources would be able to provide adequate care to more than 30 patients. Therefore, if such a physician asks for a waiver due to size and resources, I believe the number of patients they maintain should be around 30.

Response

The Department has reviewed these comments. Existing provisions in the rule address this issue and, therefore, no changes were made.

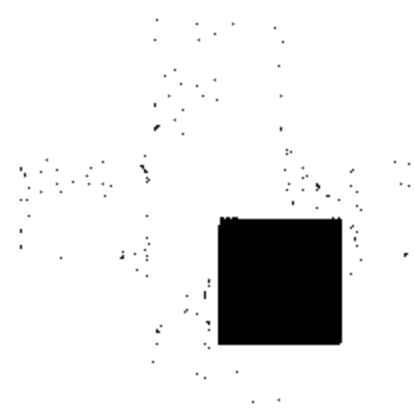
Comment

I treat opioid dependency with MAT (medication assisted treatment) in an outpatient setting and have been doing so for 7 years. I am also the Health Officer for the Berkeley County Health Department. I could spend hours dissecting the legislation related to SB454, but I really cannot afford the time to do so. What I will say is that this bill will dramatically reduce the availability of treatment for opioid dependence in our state and will likely result in ever more overdose deaths. I am now strongly considering relocating my opioid dependency treatment practice to another state because of this bill. At a

time when we should be making efforts to have more physicians treat the disease of opioid dependency, this bill will cause physicians to run from it. Here is an excerpt from AMA Morning Rounds. "AMA chairwoman urges insurers to expand coverage for opioid addiction Patrice A. Harris, MD, chairwoman of the American Medical Association, writes in a letter to the editor of the Hartford (CT) Courant (8/1) that the AMA concurs "with Aetna medical officer Dr. Mark Friedlander that we need to increase access to medication-assisted treatment for patients with substance use disorders." She says the AMA is also urging "Aetna, Cigna and all other payers in Connecticut to remove barriers to evidence-based care, including limits on physical therapy, cognitive behavioral therapy, psychiatric care and other multimodal therapies that may be appropriate." Harris adds that in order to effectively combat the opioid epidemic, "physicians must continue to play an active role in treating our patients using evidence-based care, and that also means insurance policies must provide our patients with the benefits, coverage and access necessary for that care." SB454 does nothing to increase access to MAT, it will only do the opposite. This bill will only further West Virginia's position as the leader of opioid overdose deaths in the nation. It is sad that our Governor and Legislature have been persuaded into thinking this bill will do otherwise.

Response

The Department has reviewed these comments. This comment is general in nature and offers no specific areas for amendment.



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August 5, 2016

M. Katherine Lawson, Inspector General
State Capitol Complex
Building 6 Room 817-B
Charleston, WV 25305

RE: Comments on Proposed Rule 69 CSR 12

Dear Kathy:

Please consider the following comments which are being submitted on behalf of the West Virginia Behavioral Health Care Providers Association in regard to Rule 69-CSR-12 *Medication Assisted Treatment –Office Based Medication-Assisted Treatment* which has been put out for public comment. The Association believes strongly that there needs to be regulation of opioid-based medication assisted treatment and that regulations can be developed in a fair and balanced manner. The draft rule released for comment however, is duplicative in nature for many of our members and consequently will lead to both increased costs and decreased access to a badly needed treatment modality.

Association members that provide this treatment option are already licensed by the Office of Health Licensure and Certification (OHFLAC). Yet, there is no recognition of that licensure process and the requirements for behavioral health centers to get their behavioral health license. Senate Bill 454 requires certain items which are also requirements under the existing laws and rules governing behavioral health centers. Instead of recognizing these items the proposed rule requires duplication of efforts which will lead to increase costs. We respectfully request that comprehensive community-based behavioral health centers and other licensed behavioral health centers be waived from all requirements found in the proposed rule that are also requirements of a behavioral health license.

SB 454 sets the requirements and leaves it to the state to determine compliance. If consideration is given to our recommendation, the cost of operating under this rule for the providers will be reduced. State-funded enforcement costs would also decrease.

Also, it appears that the proposed rule does not differentiate between office-based medication-assisted treatment and the existing rules related to methadone treatment. The rule needs to be rewritten to reflect what an OBMAT provider actually does, e.g. our members do not dispense the medication. Nor

should they be required to provide the same level of oversight as is needed for methadone treatment. Our comments attempt to identify all such issues but our general take is that much of the proposed rule is based on the existing methadone rule but that the two are not clinically comparable.

For our members, medication-assisted treatment is but one of many services provided and in fact is a small service in terms of patient volume and revenue generated. Yet the requirements in the proposed rule do not recognize this fact and would mandate certain staffing patterns, hours of operation and provider coverage. Provisions such as these need to be modified or eliminated; otherwise it will no longer be financially viable to provide this service at the expense of other services. A number of our concerns are detailed below but we strongly recommend that the DHHR and Legislative Rule Making Review Committee form a workgroup to more fully address these issues.

There needs to be a balance between regulation, access to care, and cost. The proposed rules as they stand create a regulatory burden that will decrease access to substance abuse treatment; however we believe a workgroup, working diligently, can develop a workable solution that assures accountability and access at a reasonable cost for the provider and more importantly for the state.

The rule regularly refers to days or hours of operation for the OBMAT program. This is clear when the clinic exists only to provide medication assisted treatment, however many providers, including the community mental health centers, operate and provide a variety of services. The proposed rule should be revised to clarify that these operations references only apply when OBMAT services are being provided.

Also, we believe there is a disconnect between the proposed rule and the state's Medicaid program with respect to what Medicaid will pay for and what the rule requires. For example, the rule requires assessments and plans of care to be frequently updated - every 90 days and in some instances more frequently. Medicaid reimburses for such assessments and related planning services at this level of frequency only for "coordinated care" services - MAT is not currently considered such a service. While we understand reimbursement and regulation are two separate items, a more patient-friendly and provider-friendly if DHHR's reimbursement policies and its regulatory policies were as consistent as possible. Changes to the proposed rule should be made to reflect minimum regulatory requirements that are paid for by Medicaid.

The following narrative highlights additional concerns of the Association.

Section 69-12-2. Definitions.

The definition section only incorporates the definitions found in code by reference. We recommend the definitions be inserted into the rule. This makes it easier for businesses operating under a regulation to follow the regulatory framework and better understand the statutory language supporting it.

In particular we believe the following definitions from SB 454, at a minimum, should be included in the regulation:

“Medication-assisted treatment” means the use of medications and drug screens, in combination with counseling and behavioral therapies, to provide a holistic approach to the treatment of substance use disorders.

(This will provide the reader a clearer picture of the legislature’s intention for a program of treatment.)

“Medication-assisted treatment program” means all publicly and privately owned opioid treatment programs and office based medication-assisted treatment programs, which prescribe medication-assisted treatment medications and treat substance use disorders, as those terms are defined in this article.

(This will provide reader with the definition the legislature had for Medication Assisted treatment and will limit confusion.)

“Medication-assisted treatment medication” means any medication that is approved by the United States Food and Drug Administration under section 505 of the Federal Food, Drug and Cosmetic Act, 21 U. S. C. § 355, for use in the treatment of substance use disorders that is an opioid agonist and is listed on the schedule of controlled substances in article two, chapter sixty-a of this code.

(During legislative consideration of this issue the drugs naltrexone and naloxone were excluded from SB 454. Both of these drugs are used for the treatment of opioid addiction but neither contains an opioid and consequently they are not listed on the schedule of controlled drugs. Absent this definition being inserted in the proposed rule we believe the rule could be interpreted by future regulators to include programs which utilize naltrexone and/or naloxone. The proposed rule is addressing medications used in long-term treatment that contain the active ingredient buprenorphine. Including this definition assures legislative intent is followed.)

“Office based medication-assisted treatment” means all publicly or privately owned medication-assisted treatment programs in clinics, facilities, offices or programs that treat individuals with substance use disorders through the prescription, administration or dispensing of a medication-assisted treatment medication in the form of a partial opioid agonist or other medication-assisted medication approved for use in office based medication-assisted treatment setting.

(Including this definition clearly establishes the scope of what the legislature intended to be regulated and will reduce confusion for the reader.)

2.32. Misuse or Non-Medical Use -- All uses of a prescription medication or substance other than those that are directed by a physician and used by an intended patient within the law and the requirements of good medical practice.

We have concern with this definition as it implies that any medication prescribed by anyone other than a doctor is defined as misuse or non-medical use. The legislature, in its most recent session, provided APRNs independent practice authority including the authority to write prescriptions without a collaborative agreement. Currently other providers such as P.A.s and optometrists have certain prescriptive authority. We recommend dropping physician and inserting provider as provided under their scope of practice.

4.2.a. Develop and implement rule and regulations regarding the registration and oversight of OBMAT programs;

We recommend this language be clarified to assure that any rule or regulation developed and implemented go through the legislative rule making process and that passage of this proposed rule as part of a DHHR omnibus rules bill during a legislative session does not provide DHHR the authority to promulgate rules independently of the legislature.

5.3.a. Treatment at the CSU is for no more than 7 days; and

We appreciate the exemption for Crisis Stabilization Units as they are using the drug for detox and not ongoing treatment. In some cases when there is a comorbid disorder it may take longer than 7 days to detox, we would ask that the time limit be increase to 14 days. We support the other qualifiers that are found in the rule as it relates to CSUs.

7.3.e. The medical director shall practice 75 percent of the hours in which the OBMAT program is operating each week in order to ensure regulatory compliance and carry out those duties specifically assigned to the medical director. Nothing in this rule prohibits an OBMAT from designating co-medical directors.

The rule indicates the medical director must practice 75 % of the hours the program operates. In the case of outpatient clinics where MAT is only one component of the services delivered, the 75% requirement should only be applied to the hours of operation for the MAT program itself, and NOT to the hours of operation for the entire clinic for other programs. The use of telehealth should count toward meeting the 75% requirement. Also, if an OBMAT provider is using a third party for counseling this restriction is not workable. The percentage should be tied to the time medical service being provided within the OMBAT program.

7.5.c. Each OBMAT program's policies and procedures shall establish ratios of primary counselors to persons served that are adequate to allow sessions to occur as mandated and that will allow persons served access to a primary counselor, either on site or by referral, but there shall be at least one counselor for every 50 patients in the program.

Legislating staffing requirements sets a dangerous precedent. The legislature has avoided legislating ratios in hospitals, nursing homes and other health providers. We believe the 50 number found in the rule is arbitrary. The key is adequate staffing for the patient base to be served. We would ask that the ratios either be placed in law for all providers or dropped from this rule.

6.5.a.1. The secretary determines that the application is deficient in any respect

The standard of “in any respect” is not a reasonable standard and recommend that this language be re-worded to read “the application is significantly deficient”

7.5.g. An experienced counselor newly employed from another MAT program may be exempt from the mandatory initial training required by this rule, if the program is able to verify and document that mandatory initial training has been received within the previous two years.

We believe that if an individual has met training requirements and that training is documented he/she should be able to work and don’t understand the imposition of the “previous two years” requirement. If they had not switched jobs they could still provide care. We strongly recommend that the above language be changed and further recommend the following:

7.5.g. An experienced counselor newly employed from another MAT program may be exempt from the mandatory initial training required by this rule, if the program is able to verify and document that mandatory initial training has been received within the previous two years previously.

8.1.c.2. The program shall establish procedures for emergency access to dosing information 24 hours a day, seven days a week. This information may be provide via an answering service or other electronic measure. Information needed includes the patient’s last dosing time and date, and dose.

The proposed language is not clear and raises a number of questions. Who are these emergency access procedures for – patients; other MAT physicians; MAT staff? How does this requirement comply with confidentiality requirements? It seems like this is more appropriate for a methadone clinic that actually doses the medication.

8.2.c. The OBMAT program shall document in the patient’s record any rejection of prior authorization, rejection of a submitted claim for written denial from a patient’s insurer or West Virginia Medicaid denying coverage for opioid treatment.

This language should be changed to clarify that clear this is ONLY required if payment will be cash basis, otherwise it is an unneeded. We suggest the following change:

8.2.c. The OBMAT program shall document in the patient’s record any rejection of prior authorization, rejection of a submitted claim for written denial from a patient’s insurer or West Virginia Medicaid denying coverage for opioid treatment if the OBMAT program intends to collect payment on a cash basis.

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

This is not applicable when electronic records are used. These programs are subject to HIPPA and other state and federal privacy laws all records must be kept in a secured manner. We suggest the following language change:

8.3.c. A secure room and lockable equipment for patient records or other appropriate security mechanisms for electronic records;

8.6 Community Relations

This section appears to be written to address the concerns with methadone and note that there are nuisance and zoning laws that deal with what this section wants to accomplish. This will require at least one new staff person and will be expensive. This is not required of physical health and is discriminatory towards mental health, continuing to foster an unfortunate stigma.

8.7 Emergency Preparedness

OMBAT is an outpatient program and does not dispense medication. As with other provisions of the proposed rule, we believe these requirements may be more applicable to methadone programs. The language should be eliminated or altered to reflect the operations of OBMAT programs.

12-9. Facility Construction and Renovations; Life Safety Policies and Procedures

Throughout this section the word “dose” and “administered” appear. OMBAT does not dispense medication. We recommend that sections 9.5 and 9.6 be rewritten to be reflective of what an OMBAT actually does versus, e.g. a methadone Clinic.

12-13. Reports and Records

This section requires a significant number of data reports that need captured and reported by an OMBAT program. We agree that data should be kept and reported however, the required information is excessive. We would ask that a workgroup be established to determine what data is needed to be reported on that will actually be read and acted on. For many of our members the experience has been that data collection and reporting is required in rules but none of it is ever used. Businesses should not be burdened with the cost of unneeded data collection and reporting.

12-16. Medication Security, Storage, Administration and Documentation

This section is another which we believe is not necessary or appropriate for an OBMAT program. The section should be completely rewritten to reflect OBMAT programs do not dispense medication. There needs to be documentation but it needs to be appropriate.

13.2.a.2. The number of patients who have been continually receiving medication-assisted treatment in excess of two years, including the total number of months of treatment for each of these patients;

Our members often do not know and are unable to verify which patients may have received treatment from other providers. This is an even more significant problem in border counties where other state monitoring systems are not integrated with West Virginia's. Even if the information required in the proposed rule is provided there is no way to validate its accuracy. We would suggest the following:

13.2.a.2. The number of patients who have been continually receiving medication-assisted treatment from the OBMAT provider in excess of two years, including the total number of months of treatment for each of these patients;

13.2.a.7. Statistics demonstrating program compliance with the random drug testing requirements of section 33.6 of this rule;

There is no section 33.6.

16.4.a. Each OBMAT program shall have a procedure through which the patient can discuss dosages of medication he or she receives with appropriate staff members regularly and upon request. This procedure shall be clearly described to the patient during orientation, upon admission and at least annually thereafter. A written explanation of the dosing procedures shall be initialed and dated by the patient and maintained in the patient chart and individualized treatment plan of care.

We believe this proposed language is more applicable for methadone programs given the references to dosages. In an OBMAT program the provider issues a prescription that is filled by the patient at a pharmacy where the pharmacy provides counseling on the medication. We also recommend dropping **“and individualized treatment plan of care”** from the language. We believe that prescription-related information should be maintained in the patient chart as it is the most up-to-date patient record which eliminates confusion.

16.5. An OBMAT program and its physicians shall not dispense or administer medication-assisted treatment drugs on site.

There may be OBMAT providers that have residential substance programs where providers deliver medication that is prescribed by a doctor and filled by a pharmacy to a resident. The resident self-administers the medication. This prohibition could have significant impact on these residential programs. The language needs to be modified and rewritten to allow these facilities to provide services. In addition, OBMAT providers may also have short term detox programs where they do dispense Buprenorphine. These are short term programs, generally under 30 days, following which the patient is referred to an OBMAT program. The proposed rule should recognize these current programs not negatively impact them with further requirements.

18.1.i. To be given a copy of the initial assessment, written acceptance into the program; or, in the case of denial of admission, a full explanation as to the basis of the denial, and a referral to another OBMAT program based upon the results of the initial assessment;

We recommend adding “upon request” to this provision.

19.7.i. The initial and post-admission individualized treatment plans of care, and any amendments, reviews or changes to the plans;

We recommend changes to this section consistent with Section 25.5

19.7.i. The initial and post-admission individualized treatment strategies or plans of care, and any amendments, reviews or changes to the strategies or plans;

19.7.l. Coordination of care agreements signed by the patient, program physician and primary counselor;

Coordination of care agreements are not currently required when the physician and counselor are employed by the same organization. We recommend the following change:

19.7.l. Coordination of care agreements when applicable signed by the patient, program physician and primary counselor;

19.7.p. Documentation that the patient was provided with a copy of the program's rules and regulations; a copy of the patient's rights and responsibilities; a copy of the detoxification treatment plan option, if applicable; a copy of the patient's individualized treatment plan of care; a copy of the patient's goals; and documentation that each of these items was discussed with the patient;

We would recommend adding "treatment strategy" to this section in order to be consistent with Section 25.5 and recommend the following change:

19.7.p. Documentation that the patient was provided with a copy of the program's rules and regulations; a copy of the patient's rights and responsibilities; a copy of the detoxification treatment plan option, if applicable; a copy of the patient's individualized treatment plan of care or treatment strategy; a copy of the patient's goals; and documentation that each of these items was discussed with the patient.

20.2. Any individual seeking admittance to the OBMAT program shall undergo a pre-admission initial assessment in order to determine whether the person meets the criteria for admission to an OBMAT program. The initial assessment, consisting of a physical examination and an intake screening, shall be conducted by the medical director, an approved program physician or a supervised physician extender. The initial assessment shall focus on the individual's eligibility and need for treatment and shall provide indicators for initial dosage level, if required and if admission is determined appropriate. The determination of admission eligibility shall be made using accepted medical criteria such as those listed in the latest approved version of the Diagnostic and Statistical Manual for Mental Disorders.

The current Medicaid rule allows for non-physician designees to complete **the intake screening** portion of the initial assessment with review and approval by physician. The initial assessment, consisting of a physical examination and an intake screening, shall be conducted by the medical director, and approved by the program physician or a supervised physician extender. We recommend that the proposed rule be changed to reflect that **the intake screening** may be conducted by a non-physician designee but must be reviewed and approved by a physician or supervised physician extender consistent with the Medicaid program rules.

20.21. Patient Transfers.

20.21.a. OBMAT programs shall accept patients transferring from another OBMAT program within the state of West Virginia, if:

20.21.a.1. The OBMAT program accepting a patient voluntarily transferring from another OBMAT program shall provide documentation that the patient's medical record and reasons for the transfer was sought from the patient's previous OBMAT program; and

20.21.a.2. The patient is in compliance with readmission policies for patients who have been administratively detoxified.

Comment: No other medical provider in this state for non-emergent care is required to accept patient transfers. Each program should be allowed to determine if it wants to accept a patient transfer. The physician or program personnel may have just cause to not serve a particular patient. This section should be deleted. It also does not recognize a practice may be full or not taking new patients.

21.2. When practicable, the OBMAT program shall obtain a written consent for release of information from the patient in order to check the records of every OBMAT program within 100 miles of the program site so as to ensure that the patient is not currently enrolled in those programs as well. The request for information may be made by telephone, fax or e-mail. The release of information shall state that only prior admissions may be the subject of inquiry, not contacts without admission. The OBMAT program shall protect patient confidentiality at all times and with all procedures used in acquiring medical or health information.

Unlike Methadone there are a significant number of OBMATs we are not sure how our members check every provider within 100 miles. Also it may be a violation for OBMAT provider to require the release of this type medical information as a condition of treatment. The provider not the state would be subject to liability and federal fines. This is an erroneous requirement, the drug screen will show if the client currently is under treatment.

25.1. Each OBMAT program shall provide adequate medical, counseling, vocational, educational, recovery and other assessment and treatment services. These services must be available onsite at the facility or on a referral basis to outside providers and the medical director at an OBMAT program must be able to document that these services are fully and reasonably available to patients and comply with all federal and state laws, rules and regulations.

Comment: The rule requires an OBMAT program to provide "adequate "vocational, educational" services while these may be needed services for those in recovery, they are not the responsibility of the OBMAT provider to supply these. These are not health services and will probably not be reimbursed by any health payer. We would ask that they be deleted from the rule.

25.5. Within seven days of the admission of a patient, the OBMAT program shall complete a post-admission initial assessment, an initial individualized treatment strategy or plan of care and a coordination of care agreement.

The coordination of care agreement in Behavioral Health industry is currently used when the treating physician and treating counselor do not work in the same agency. We would suggest this language be changed as follows:

25.5 Within seven days of the admission of a patient, the OBMAT program shall complete a post admission initial assessment, an initial individualized treatment strategy or plan of care and a coordination of care agreement, provided a coordination of care agreement is only required when the treating physician and treating counselor work at different agencies/programs.

Section 25.5 allows **for a treatment strategy** or plan of care however throughout the rest of the rule (example 27.2.b) there is no more mention of the treatment strategy in place of the plan of care. We recommend the proposed rule be reviewed to ensure that in all places where a plan of care is mentioned that the option of a treatment strategy be included as well.

25.11. Services provided by an OBMAT program should adhere to recovery initiatives promoted by federal and state laws, rules and regulations and the protocols and guidelines of approved authorities. Recovery initiatives include assistance in overcoming or managing a patient's substance use disorder or other diseases; encouraging a patient to live in a physically and emotionally healthy manner; ensuring that the patient lives in a stable and safe place; engaging the patient in meaningful daily activities, such as job, school, volunteerism, family caretaking or creative endeavors; and assisting the patient in obtaining the independence, income and resources to participate in society and in developing relationships and supportive social networks.

This is a good statement and it is more of a legislative finding than what should be in a regulation. It does not provide specific targets that would guide a provider. This should be the goal, but the rule does not provide a way to measure compliance as such it should be removed or modified.

12-26. Counseling

Counseling should be a part of the process to recovery when using MAT, however the counseling section raises several issues and it should be modified.

We would ask the OHFLAC and BMS sit down on the counseling standards and time frames so that the either the rule mirrors the Medicaid framework or Medicaid follows OHFLAC. Both entities are under the umbrella of DHHR and there should be coordination. For example the counseling time frames in 26.8 do not match what BMS will pay for.

Also if an OBMAT arranges counseling with a third party at separate location from the OMBAT the Medical Director should not be required to be present during that counseling. Maybe the best solution

would be to stipulate the 75% kicks in when OBMAT services that are physical in nature are being performed.

26.7.a. Reflect an appropriate clinical mix of gender, race and ethnicity representative of the population served;

This is a great standard if West Virginia did not have a workforce shortage in this field, the words "to the degree possible based on available staff" should be added.

Section 69-12-27. Provision of Coordination of Patient Care; Post-Admission Assessment and Initial Plan of Care.

12-27. Provision of Coordination of Patient Care; Post-Admission Assessment and Initial Plan of Care.

This section does not reference the use of a treatment strategy.

27.2. Initial Post-Admission Assessments.

27.2.c. The initial post-admission assessment shall consist of a comprehensive medical assessment and include documentation of:

27.2.c.7. A tuberculosis screening;

27.2.c.8. A screening test for syphilis;"

The initial post assessment requires a tuberculosis and syphilis screening. These are tests not often medically necessary or regularly performed by medical personnel during MAT induction. We would ask that both 27.2.c.7 and 27.2.c.8 be removed from the requirements.

28.2.d. Other appropriate and permitted collateral sources.

Not sure what this is?

29.10.a. The coordination of care agreement shall be signed by the patient, program physician and primary counselor. If a change of program physician or primary counselor takes place, a new agreement must be signed.

This is only necessary when these staff persons are NOT employees of the same company.

We would recommend

29.10.a. The coordination of care agreement shall be signed by the patient, program physician and primary counselor when the primary physician and counselor are not employed by the same

company. If a change of program physician or primary counselor takes place, a new agreement must be signed.

33.2.d.3. When using urine as a screening mechanism, all patient drug testing shall be observed

When higher volume urine drug screening is utilized, this may be impractical, yet we don't want to force fewer urine screens if observations cannot be done for all.

We would suggest

33.2.d.3. When using urine as a screening mechanism, at least one random monthly urine drug screen shall be observed

33.2.e.5. Cocaine;

Please add (or metabolites of same)

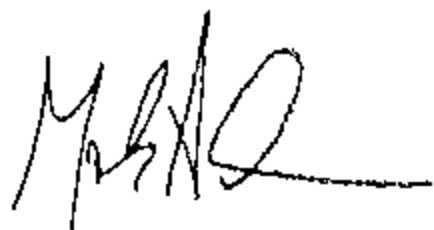
33.2.e.7. Tetrahydrocannabinol, delta-9-tetrahydrocannabinol, dronabinol or other similar substances;

Please add (or metabolites of same)

Also as part of our comment is an attached PDF which compiles the above and includes additional comments from individual members of the association as it relates to this rule.

It is important that the final proposed rule adopt quality treatment standards that will improve the health of West Virginia citizens who need help. In its current form, the proposed rule may become a barrier to treatment. We offer our assistance to help modify the rule in order to develop a workable rule that meets the stated purpose of the legislation without reducing access to needed substance abuse services.

Sincerely,

A handwritten signature in black ink, appearing to read 'MAD', with a long horizontal flourish extending to the right.

Mark A. Drennan
Executive Director

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Morgantown, WV 26508
P: 304-284-0025
F: 304-284-0031

**Valley Alliance
Treatment Services**

Fax

To: Katherine Lawson From: Erika Pullie MD
Fax: 304-558-1992 Pages: _____
Date: 8/5/16
Re: Proposed amendment 69-12

☐ Urgent ☐ For Review ☐ Please Comment ☐ Please Reply ☐ Please Recycle

**Valley-Alliance
Treatment Services (VATS)**

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M. Katherine Lawson, Inspector General
WV DHHR office ~~OF~~ Inspector General
State Capitol Complex
Building 6, Room 817-B
Charleston, WV 25305

Proposed amendment 69-12- Commentary

August 5, 2016

To Whom This May Concern,

My background is that of a board certified family doctor. In February 2014 I started working in addiction medicine at Valley Alliance Treatment Services (VATS), in Morgantown West Virginia. I've undergone training and do have Suboxone prescribing privileges. For the past 2 1/2 years I have been treating patients with opioid addiction both in our Methadone treatment program, and in our Buprenorphine/Naloxone program.

The first issue is the similarity between the two proposals. Essentially the same rules will apply for both Methadone Treatment Centers: MAT and outpatient Suboxone treatment programs OBMAT. Currently the programs are very different as the medications are very different. Apparently, these proposals have taken the methadone guidelines and applied them to Suboxone outpatient office-based treatment.

Methadone is a much stronger medication with more lethal overdose potential, than Suboxone. Methadone is considered to be a last resort treatment. While we do have a few methadone patients who travel significant distance to our clinic, most of our methadone patients live within an hour drive.

My understanding was that the national and state goal is to have more doctors treating addiction effectively. West Virginia needs to train more primary care doctors to prescribe Suboxone safely and effectively. Doctors need to be able to do this within their existing office settings. There is no way a family doctor, working out of their Family Practice office, can realistically conform to the counseling requirements laid out in 69-12 section 26.

In order to conform to these guidelines any physician would need to set up an entire behavioral health clinic including a team of counselors, case managers, nursing staff, and at least one insurance specialist. These requirements seem to have been pulled either from pre-existing methadone OTP requirements or from the practices of large behavioral health centers such as Chestnut Ridge Hospital.

Thankfully, there is an allowance on section 26.1 for the counseling to be obtained outside of the OBMAT program. The state needs to be aware if this does not translate to counseling availability in patients communities. Many patients in the OBMAT program travel long distances for the help and live in and remote rural areas with limited or nonexistent access to mental

healthcare and addiction counseling. Additionally, many people seek help for their addiction and have to work within confines of their employment schedule. Rarely will an employer allow an employee to miss work with the frequency outlined and 26.8. I have many patients who do maintain viable employment and maintain sobriety and recovery with the help of our OBMAT, despite the lack of counseling availability. Some patients are forced to work away from home for weeks at a time. Although patients may not have not been able to comply with such rigorous counseling demands as laid out by some of the larger behavioral health centers, they have indeed made significant progress in their addiction treatment when treatment can be tailored individually to patient's needs according to their work schedule and the availability of local resources.

I propose the state recognize the lack of local counseling facilities. We are in an underserved area throughout the state of West Virginia. Even in Morgantown, West Virginia where we do have Valley Mental Health services and the Summit Center as well as Chestnut Ridge Hospital, wait lists to establish care can be several months long. Considering that VATS is situated in Morgantown, and my local patients have difficulty accessing behavioral health care, it should be self evident that doing so presents a prohibitive obstacle for those who travel several hours just to keep their doctor appointments.

I propose the state allow leeway allowing patients to receive credit for a group activities such as narcotics anonymous/ celebrate recovery meetings where this is applicable.

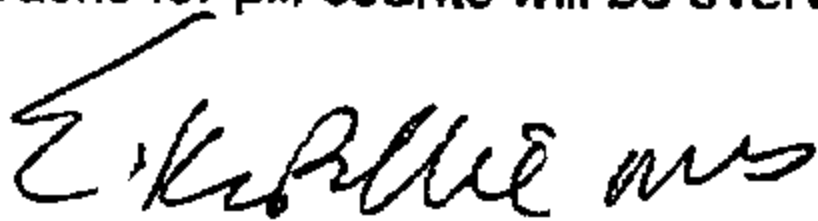
Finally, I think it's important to remember that addiction treatment services are ultimately about harm reduction. Clearly, patients do have significant harm reduction with regular doctor appointments, drug screens and when given access to the medication that can help them change their lives. With the help from Suboxone therapy, patients stop abusing drugs, stop high-risk behavior, stop spreading disease by IV drug use. All of this causes and decreased crime while helping people who suffer from addiction maintain gainful employment and get their lives back on track.

While I applaud your efforts to ensure quality addiction services for anybody in medication assistant addiction treatment, it seems the degree of stringency in the regulations as outlined in the amendment 69 – 12, will make it almost impossible for a family physician to treat addiction in their office. Therefore the guidelines in this proposal, are in direct conflict with the interest of our citizens. West Virginia is a state in crisis with a significant population suffering from addiction. We need to facilitate expanding access to addiction therapy.

We need to decrease the obstacles to enrolling more physicians in drug treatment at local levels. Patients will be better served if they don't have to drive hours to get help. There is no way overworked Family Doctors will make the effort to pursue treating addiction if they have to comply with these guidelines to do so.

I fear that with the passage of these amendments, physicians who are currently able to treat patients individually, while monitoring regular urine drug screens, seeing patients monthly, and doing call backs for pill counts will be overwhelmed and will just give up their role in the battle.

Sincerely



Erika Pallie MD

Law Office of

Philip A. Reale, PLLC

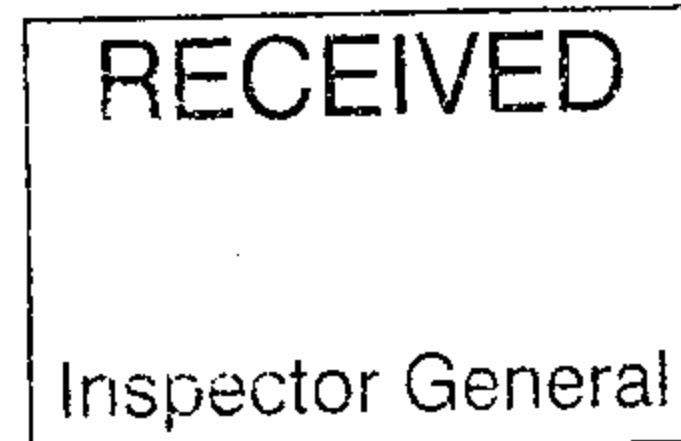
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August 5, 2016

M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex, Building 6, Room 817-B
Charleston, West Virginia 25305



RE: Comments of Ohio Valley Physicians Inc. regarding Title 69, Series 12,
Medication Assisted Treatment – Office-Based Medication-Assisted Treatment

Dear Inspector General Lawson:

Contained herein are comments offered on behalf of my client, Ohio Valley Physicians, in relationship to Title 69, Series 12, Medication Assisted Treatment – Office-Based Medication-Assisted Treatment, filed with the office of the West Virginia Secretary of State and noting a return date on all comments of August 7, 2016.

Ohio Valley Physicians headquartered in Huntington, West Virginia, with facilities in Logan, Huntington, and Ravenswood, is a group of primary care specialists dedicated to providing the finest and most up-to-date holistic and comprehensive general medical care to its communities in both office settings and walk-in clinics. Ohio Valley Physicians employs more than sixty-five West Virginians. Make careful note that the organization provides general medical care and as a component of such, offers a program of addiction treatment in conjunction with counseling services provided by companion organizations.

Ohio Valley Physicians was founded in 1999 as a primary care provider organization, but soon thereafter realized that the pervasive substance abuse problem in its service area was so intrinsically a part of the treatment needs of patients with other maladies, that the treatment of routine medical conditions of many of their patients could not be properly addressed without addressing their substance abuse issues

simultaneously. Therefore, substance abuse treatment was added as an essential component of the practice in order to address the abundance of dual diagnoses in the patient population.

While there are any number of legitimate and effective substance abuse treatment programs in West Virginia, Ohio Valley Physicians has quickly risen through the ranks to become one of the most respected office-based medication-assisted treatment providers in our state. A prime example of their successful model is demonstrated by their recent CARF Accreditation as an integrated behavioral health/primary care provider, a singular distinction held by Ohio Valley Physicians and no other in West Virginia.

CARF, or the Commission on Accreditation of Rehabilitation Facilities, is an international, independent, nonprofit organization whose entire focus is to evaluate the quality of healthcare and to award accreditation to those who meet CARF's very high standards and demonstrate a commitment to providing the best possible service. CARF Accreditation involves a very thorough 10-step process which includes interviews, evaluations, on-site inspections and surveys. Receiving CARF Accreditation requires a commitment to excellence that Ohio Valley Physicians has consistently and resolutely demonstrated.

Because my client operates highly respected medical practices, they welcome reasonable regulations for all healthcare services, including office-based medication-assisted treatment for substance abuse. In other words, the operations of Ohio Valley Physicians are not singularly focused on dealing with opioid addiction in the manner of a Methadone clinic.

Further, my client appreciates the opportunity to have been involved in the fine tuning of SB 454, Licensing and regulating office-based medication-assisted treatment programs for substance use disorders, which was enacted during the 2016 Regular Session of the legislature. They truly appreciate the sentiment of the Legislature that a more robust means of arresting the opioid addiction crisis in West Virginia can be found in the more holistic approach to treatment with complimenting conventional principles of quality health care. The assessment from the perspective of Ohio Valley Physicians is that SB 454 is widely considered by providers to be a very sound piece of legislation. The

amount of stakeholder input into the development of SB 454 was remarkable and resulted in legislation reflective of practical concerns expressed by stakeholders.

Unfortunately, there was no similar assessment of the agency rule for Office Based Medication-Assisted Treatment as, in many instances, the rule fails to capture the essence of what office based treatment involves and the operating mechanics of the same. Had there been an opportunity for stakeholders to provide practical perspective in the development of the Office-Based Medication-Assisted Treatment rule now under consideration, that may not be the case. The subject matter addressed by the rule and SB 454 as it relates to office-based medication-assisted treatment is one of first impression in West Virginia. Without the active and informed input of those who have already demonstrated accrediting organizations' positive evaluation for their operations and services extended, an opportunity has been missed to generate a rule which would have more acceptance in the regulated community. In fact, there is genuine fear that the rule as currently cast will likely achieve a result not desired by SB 454 and that would be for there to be less office-based services in West Virginia rather than more. Accordingly, the comments provided hereafter are comprehensive and quite extensive.

Before making specific comments on the rule in question, it is important to provide some general observations to the rule as a whole and, although perhaps unintended, the likely implications. First, Ohio Valley Physicians is keenly aware, perhaps more so than most, of the gravity of the drug epidemic in our state. It is a pervasive issue throughout its service area. Some medications prescribed to treat drug abuse have found their way into the illegal markets, further contributing to the problem that SB 454 is designed to help cure. There is an understanding that legitimate treatment practices are competing against bad actors who sell treatment medications under suspect circumstances. It is doubtful that SB 454 and the final rule will ever reach the bad actors dealing illegally in prescription painkillers and irresponsible contributors to such. There is genuine recognition that action is desperately needed in order to overcome the difficult challenges substance abuse imposes on our population and the devastating impact it has on our communities. There is appreciation for the promise of SB 454 for responsible treatment of those afflicted with opioid addiction and the refined development of this rule as positive efforts to address the many layers of difficulties that

exist in the scourge of substance abuse. However, in order for the rule to responsibly and reasonably address the subject of office based medication-assisted treatment for drug abuse, there is a tremendous amount of re-thinking that must be done under a collaborative arrangement with those who uniquely know, understand and responsibly practice office-based medication-assisted treatment programs.

The inherent goals of the Office-Based Medication-Assisted Treatment rule are worthy ones. Ohio Valley Physicians is in complete agreement with the proposition that medication assisted treatment needs to be administered safely, correctly and in conjunction with specialized counseling services. However, there is a fear that the requirements contained in this rule far exceed current professional standards of practice to the extent that the cost and sheer difficulty of compliance will cause respectable practitioners to simply stop providing addiction treatment services, thereby reducing access to substance abuse treatment at a time when circumstances in our state demand increased access to professionally administered treatment. Further, while the utilization of OBMAT is an intentional departure from opioid treatment programs, a departure proven more successful in holistically treating the patient, contained within the rule are several attempts to impose Methadone related regulations on medical professionals who practice in OBMAT programs; regulations that simply do not apply to office-based treatment. Implementing such stringent and excessive regulatory requirements as are currently contained in the draft rule has the very real potential to not improve services, but to eliminate them entirely by the regulation of legitimate doctors, counselors, psychiatrists, psychologists, mental health professionals, etc. which exceeds recognized practice standards and imposes costs which are prohibitive to West Virginia small clinics and practitioners.

Just one example of the additional costs that will be associated with compliance are certain examination and testing requirements of patients which far exceed coverage limits imposed by Medicaid and what private insurers will pay, and in some cases, what the federal government recommends. Thus, the effect is the imposition of unfunded mandates on physicians and behavioral health professionals who are deeply invested in time, money and spirit to help treat the substance abuse problems facing our communities. These essentially unfunded mandates will undoubtedly make it cost

prohibitive for many treatment programs to operate, especially those whose only sources of income are Medicaid payments, grants and benevolent donations. This is not to say that clinics operated by providers such as Ohio Valley Physicians will not continue to provide a wide spectrum of medical services to patients generally, it just means that it is not reasonable to expect them to provide addiction treatment programs which are cost excessive under a set of regulations which seeming do not recognize the very nature of the office-based practice methodology sought to be developed in West Virginia as a combatant to the pervasive opioid addiction problem in the state. There can be no question but what the clear intent of the legislature was to progressively pursue the development of programs to treat those with opioid addictions which work in a holistic manner to achieve and maintain the sobriety of their patients.

And further still, the licensing requirements and other provisions contained in 69 C.S.R. 12 will not prevent illegal actors and unregistered laymen and women, who are perhaps addicts themselves, from illegally distributing or selling Suboxone from the bed of a pickup truck in a retail parking lot, or a cleverly disguised illegal clinic operation from dispensing controlled substances for cash. Imposing regulations which may exceed what is provided for in statute and which have a cost of compliance which is unaffordable on commendable performers may not be the answer. Rather, perhaps it is the actual enforcement of reasonable regulations which should be the higher priority, as the illegal actors in this space aren't going to follow any recognizable rules.

Finally, before detailing specific comments relating to the rule, it is necessary to mention the recent passage by Congress of the Comprehensive Addiction and Recovery Act (CARA) of 2016, a goal of which being *the expansion of access to treatment*. There are a number of issues addressed in CARA that, once fully implemented, would overlap and perhaps even conflict with the provisions of 69 C.S.R 12. For example, CARA aims to modify existing regulations to permit nurse practitioners and physician assistants to administer medication-assisted treatment for opioid use disorders, while also increasing the number of patients whom a qualified physician can prescribe buprenorphine from 100 to 275 – again all in an effort to increase access.

The U.S. Department of Health and Human Services is currently seeking stakeholder comments regarding education and training programs, the requirements for

which are likely to change. The utilization of Distance Learning and Telemedicine is set to increase in order to assist rural areas in addressing the opioid epidemic. While the specifics of these and many other policy initiatives are still unknown, it is safe to say that the federal regulations relating to medication-assisted treatment will indeed be changing and unquestionably become part of practice regimens and business models in ways different from that of 69 C.S.R. 12. Regulatory consistency should be a goal of policymakers if the objective is to have professional and effective substance abuse treatment, facilitating responsible providers with a known operating environment and an aggressive enforcement program for purveyors of illegal prescription drugs.

Consideration by the Department of Health and Human Service should be given to minimizing 69 C.S.R. 12 to allow for consideration of developing federal policy being shared in the same subject area to avoid casting West Virginia providers, including Ohio Valley Physicians, in the untenable position of complying with different, even conflicting state and federal regulations. Thorough examination of the federal law and its impact on office-based medication-assisted treatment in West Virginia, utilizing an open and inclusive process whereby those on the front line of providing medication-assisted treatment would seem to be the starting point. This is not a task which can be achieved overnight. It will require significant work, dedication to mission and commitment in order to achieve the desired result of a workable regulatory program that fosters much needed increased access to care, superior quality of care, accountability for performance based on statewide statistics and more. Ohio Valley Physicians would be happy to participate in any such process.

The foregoing remarks establish an important framework in which the comments should be read and considered. Organizationally, the following comments address specific sections of the rule and will include the section/s being addressed followed by the accompanying comment:

2.9. Counseling Session -- A face-to-face interaction in a private location between a patient(s) and a primary counselor for a period of no less than 30 minutes designated to address patient substance use disorder issues or coping strategies and individualized treatment plan of care.

WV Code Chapter 16, Article 5Y, the Medication-Assisted Treatment Program Licensing Act, specifically allows for the use of telehealth as long as it is permitted under a practitioner's scope of practice. It is therefore requested that language be added to this definition allowing both face-to-face interactions as well as interactions via the use of telehealth. The utilization of telehealth to extend and expand health care services, including medication-assisted treatment, to residents of rural areas of West Virginia is a much needed means of increasing access to services in the pursuit of making a generational change in West Virginia's families and communities afflicted with opioid abuse.

2.32. Misuse or Non-Medical Use -- All uses of a prescription medication or substance other than those that are directed by a physician and used by an intended patient within the law and the requirements of good medical practice.

The use of the word "physician" could prove too restrictive for the agency's intended purpose, as it does not contemplate that physician assistants and nurse practitioners may also be prescribers. We recommend changing the word "physician" to "provider" or including PAs and APRNs in the definition.

It is duly noted that new federal law suggested expanded use of PAs and APRNs as prescribers as a means of expanding access to medication-assisted treatment. It is recognized that this will expand the universe of prescribers and thus an expansion of the possibility of bad actors. However, responsible prescribers will remain as such and enforcement agencies must deal with those who act outside the bounds of law.

While it is noted that at least some of the motivation for SB 454 and the rule for which these comments are provided is to regulate the activity of medication-assisted addiction treatment to prevent illegal use of prescription drugs, those prescribers who are complicit in pill mill operations and similar illegal prescribing of opioids are not likely conformists to new laws and regulations since they have not been conformists to previous and existing laws. Their illegal conduct is the subject of other laws and governing policies which warrant aggressive enforcement.

4.2. The powers and duties of the state oversight agency include, but are not limited to, the following:

4.2.a. Develop and implement rule and regulations regarding the registration and oversight of OBMAT programs

Subsection 4.2.a. appears to grant OHFLAC rule-making authority independent of legislative action. It is recommended that this language be stricken, or at the very least amended to clarify that any rules developed by OHFLAC must advance through the proper legislative rule-making process in order to become effective.

6.1.e. Each registered OBMAT program shall designate a medical director unique to that program. The medical director shall practice at the program and be responsible for the operation of the program in accordance with the requirements of this rule. Nothing within this rule will prevent an OBMAT program from designating two co-medical directors.

WV Code §16-5Y-5(c) states that, “If the medication-assisted treatment program is accredited by a Substance Abuse and Mental Health Services Administration (SAMHSA) approved accrediting body that meets nationally accepted standards for providing medication-assisted treatment, including the Commission on Accreditation of Rehabilitation Facilities (CARF) or the Joint Commission on Accreditation of Healthcare Organizations, then the program may designate a medical director to oversee all facilities associated with the accredited medication-assisted treatment program.” As stated previously, Ohio Valley Physicians is indeed a CARF Accredited program and therefore should only be required to designate one medical director to oversee all of their West Virginia facilities. It is recommended that this code provision be referenced in this rule.

It is additionally noted that “practice at the program” as used in the rule may require definition. If it means “practice” exclusively at the program and the physician not be permitted to have broader practice interests, the economic reality may be that a

fewer number of physicians will avail themselves of the opportunity to work in much needed medication-assisted addiction treatment programs and thus have the practical effect of reducing patient access to medication-assisted treatment programs.

6.3.a. All applicants for an initial, provisional or renewed registration shall be accompanied by a non-refundable fee in the amount required by this rule. The annual renewal fee is based upon the average daily total census of the program. In addition to the set fee, the annual renewal fee shall be adjusted on the first day of June of each year to correspond with increases in the consumer price index. The base amounts for initial, provisional and renewal fees are as follows: . . .

6.3.a.3. Renewal registration fee – \$500 plus adjustment.

This section seems contradictory, as it first states that the annual renewal fee is based on the average daily total census (an almost impossible number to generate) but then states that the renewal fee is \$500 plus adjustments. This subject was raised at a meeting with DHHR representatives on June 24, 2016. At that time it was stated that the “adjustment” would be based on either the Consumer Price Index or the Consumer Price Health Index. The indication being that the \$500 renewal fee was a constant number subject to annual adjustments based on the identified replacement factors. Therefore, the average daily total census of the program is irrelevant for these purposes and should not affect the renewal fee. It is recommended that the sentence that references such be stricken. Maintaining the requirements simply adds an unnecessary administrative burden and costs associated in fulfilling the same.

6.5. Denial of Registration.

6.5.a. The secretary may deny an application for an initial, provisional or renewal registration if:

6.5.a.1. The secretary determines that the application is deficient in any respect;

It is recommended that the word “significantly” be added before the word “deficient” in order to establish a reasonable standard of review.

6.5.a.5. The OBMAT program fails to have a medical director practicing at the program location;

Again, based on WV Code §16-5Y-5(c), if a program is CARF Accredited then one medical director may be designated to oversee all facilities, thus the medical director of a CARF Accredited program may not necessarily always be practicing at a specific program location. Therefore, the provision set forth in rule is in conflict with and creates a circumstance in which the provision in rule exceeds what is provided in statute. A change in the language is recommended to conform to the provisions of the statute.

7.1. Each OBMAT program shall identify a program administrator, medical director, program physician(s), and counseling staff.

Both Chapter 16, Article 5Y, Medication-Assisted Treatment Program Licensing Act, and this rule allow counseling services to be provided by referral. Indeed, the comprehensive patient treatment desired may be accomplished through a collaborative arrangement. It should be noted that not all treatment elements have to be contained as part of the same program setting, even though all elements have to be part of a treatment plan for the individual patient. Therefore it is requested that the identification of counseling staff be optional and not required. Once again, the express provision of the proposed rule exceeds the requirements of the underlying statute and could result in reduced access for those needing medication-assisted treatment for drug addiction.

7.2.a. The administrator of an OBMAT program shall have at a minimum a bachelor's degree in an appropriate area of study and a minimum of four years of experience in the fields of substance use disorders, behavioral health or health care administration

or a master's degree in an appropriate professional area of study and a minimum of two years of experience in the fields of substance use disorders, behavioral health or health care administration; or eight years of experience in the fields of substance use disorders, behavioral health or health care administration.

As mentioned previously, limiting access to care by the overregulation of OBMAT programs is a very real concern. The requirement of a master's level professional to also have two years of experience in substance abuse disorders in order to be a program administrator greatly limits use of the pool of qualified physicians assistants and nurse practitioners who would otherwise be ideal to serve as program administrators. It is therefore requested that the requirement of two years of experience in substance abuse disorders for master's level professionals be stricken in order to ensure OBMAT programs have a sufficient group of candidates for program administrator from which to choose. Otherwise the pool of individuals uniquely qualified under the terms of the proposed rule is likely to fall short of what is needed to sustain even the current level of treatment for those needing medication-assisted treatment. It diminishes access to care when access to care is sought to be increased.

7.3.b. The medical director shall also meet the following requirements:

7.3.b.1. If the medical director prescribes a partial opioid agonist, he or she shall complete the requirements for the Drug Addiction Treatment Act of 2000; and

7.3.b.2. Demonstrate experience in substance use disorder treatment and medication-assisted treatment; or

7.3.b.3. Have a written plan to attain competence in substance use disorder treatment and medication-assisted treatment within a probationary time period as provided in section 7.3.c. herein.

According to the subdivisions contained in 7.3.b., in order for a physician to hold the position of medical director, he or she must obtain a DATA 2000 waiver **and** be either experienced or competent in substance use disorder or medication-assisted treatment. In order for a physician to receive his or her DATA 2000 waiver as required

in 7.3.b.1, SAMSHA requires a physician to hold a certification in addiction medicine or to complete SAMSHA approved training in opioid addiction, either of which would certainly constitute a demonstration of experience or competence in substance use disorder treatment or medication-assisted treatment. In order to eliminate this redundancy, it is requested that subdivisions 7.3.b.2 and 7.3.b.3 be stricken, as the obtainment of a DATA 2000 waiver should indeed be considered sufficient evidence of experience and/or competence in substance use disorder or medication-assisted treatment.

7.3.e. The medical director shall practice 75 percent of the hours in which the OBMAT program is operating each week in order to ensure regulatory compliance and carry out those duties specifically assigned to the medical director. Nothing in this rule prohibits an OBMAT from designating co-medical directors.

Requiring a specified medical director to be on site 75 percent of the time that the facility is in operation is an unnecessary hardship that would greatly limit the number of physicians willing to serve in such a position.

The comments set forth above in relationship to §6.1.e are applicable here and incorporated by reference. The practical effect of the express provision of this section of the rule is that it significantly reduces the likelihood of an adequate pool of physicians being willing to limit their practice of medicine to such a narrow field. Additionally, it involves a patient population which, hopefully, will shrink and thereby reduce the practice opportunities for those physicians willing to accept a position as a medical director of an OBMAT program. An ancillary impact is that if this provision remains and is enforced, the community at large will likely see reduced access to healthcare by physicians who make a choice to relate singularly to addiction treatment programs and not involve themselves with non-addicted patient populations.

Ohio Valley Physicians consists of a significant team of physicians and other medical professionals. Requiring one of them to focus solely on the OBMAT program instead of dedicating time to surgeries, emergencies, volunteer work, etc. would be a great disservice to the physician as well as the community at large. Also, because Ohio

Valley Physicians operates offices and clinics that also happen to treat substance abuse, there are times when medication-assisted treatment is not even being performed.

That said, Ohio Valley Physicians, except in the rarest of circumstances, would have responsible medical professionals on site at each facility. Therefore, it is requested that language be added stating “The medical director or his or her designated physician extender shall practice 75 percent of the hours in which the OBMAT is operating . . .” Adding this language would ensure that a responsible medical professional is available at least 75 percent of the time and very likely more.

And again, Ohio Valley Physicians is a CARF Accredited program and therefore should only be required to designate one medical director to oversee all facilities as provided for in statute.

7.4.d. During all hours of operation, every OBMAT program shall have present and on duty at the program at least one of the following actively-licensed health care professionals:

7.4.d.1. Physician

7.4.d.2. Physician assistant;

7.4.d.3. Advanced practice registered nurse; or

7.4.d.4. Registered nurse.

The practical reality of any program being able to comply with this provision in the absolute sense is that it is impractical. Certain exceptions must be recognized.

Though rare, there may be circumstances when an emergency causes only support staff to be available in a program office. For example, recent flooding greatly disrupted staffing at one Ohio Valley Physicians’ clinic and only a receptionist was on hand for part of a morning. Obviously no medicine was practiced at that time and the receptionist was only responsible for scheduling and phone coverage.

Unfortunately emergencies do indeed happen, sometimes requiring the services of medical professionals to be directed elsewhere. It is therefore requested that language be added to convey that one of the health care professionals listed above must be present during all hours of operation “when patients are being medically treated” in

order to address those exceptional circumstances when a medical professional may not be on site. Further, the objective of being present in the case of a physician should be achievable through telehealth and such be provided for in the rule. It is fully recognized that no medical treatment may occur when a responsible medical provider is not in attendance or available through the medium of telehealth.

7.5.c. Each OBMAT program's policies and procedures shall establish ratios of primary counselors to persons served that are adequate to allow sessions to occur as mandated and that will allow persons served access to a primary counselor, either on site or by referral, but there shall be at least one counselor for every 50 patients in the program.

As you will likely hear from other OBMAT programs, a 50 to 1 patient to counselor ratio is next to impossible to achieve for any number of reasons. One significant reason may be that it effectively eliminates the ability to utilize group therapy sessions, an often used practice in the treatment of individuals afflicted with addiction issues. While Ohio Valley Physicians does not provide counseling services, the cold hard facts are that our state already faces a critical shortage of substance abuse counselors. Placing such a strict restriction on the number of patients that each is allowed to treat and not recognizing the need for group counseling will undoubtedly result in limiting access to care and be counterproductive to the purposes of SB 454 and that of West Virginia addressing the severe drug addiction problem in a segment of its population.

Additionally, section 26.8 outlines a very specific counseling schedule that must be followed based on a patient's status in the program. As an example, after a patient's initial 90 days in the OBMAT program, he or she must receive counseling services twice a month for the remainder of his or her first year in the program. Should a certain counselor's 50 patients all require twice monthly sessions at a half hour each (a very likely scenario), that counselor would only be allowed to provide 50 hours of counseling services per month. The 50 to 1 ratio essentially could prevent a counselor from practicing more than a little over a week's worth of work in a month's time, resulting in

an extreme waste of time and talent and making counselors even less likely to provide substance abuse treatment. Again, the practical effect of the 50 to 1 ratio is that it is impractical and counterproductive to the purposes of SB 454.

It is for these reasons that the 50 to 1 patient to counselor ratio should be stricken from this rule.

8.1.c.1. The program shall notify the individuals receiving medication-assisted treatment services in writing at least 30 days in advance of their intent to close on Sunday or permanently change service hours. All individuals shall receive an orientation addressing policies and procedures, and this orientation shall be documented in the individual's record prior to receiving mediations; and

While Methadone clinics may be required to be in operation seven days a week, Ohio Valley Physicians operates professional offices and clinics that provide medical care. These are distinctively different types of delivery of addiction treatment and deserve separate treatment in rule. The treatment Ohio Valley Physicians provides does not require daily dosing regimens. Therefore it is not necessary or appropriate for them to notify patients individually if they are closed on Sundays (which they are) and instead should simply be required to post regular office hours. Again, a disconnect exists between the purpose of regulating an OBMAT program and a Methadone clinic. It is requested that the language related to Sunday closures be stricken or substantially modified, and in the unlikely event that regular office hours would change for any reason, patients be notified accordingly.

8.2. Payments for services rendered may be made either by West Virginia Medicaid, private insurance, or by cash as described in 8.2.d.

8.2.a. The OBMAT program shall be eligible for, and not prohibited from, enrollment with West Virginia Medicaid and other private insurance.

8.2.b. Prior to directly billing a patient for any opioid treatment, the OBMAT program must receive either a rejection of prior authorization, or rejection of a

submitted claim or a written denial from a patient's insurer or West Virginia Medicaid denying coverage for such treatment.

8.2.c. The OBMAT program shall document in the patient's record any rejection of prior authorization, rejection of a submitted claim for written denial from a patient's insurer or West Virginia Medicaid denying coverage for opioid treatment. The OBMAT program shall also clearly document in the patient's record if the patient has no insurance or has voluntarily and with full knowledge of the financial obligations, including all treatment costs, requested a claim not be submitted to their insurer or West Virginia Medicaid. When any instance described in this section regarding direct billing and acceptance of cash payments from a patient occurs, the OBMAT program shall clearly document in the patient's record the rationale and medical necessity for acceptance into the program.

8.2.d. The OBMAT program may directly bill and accept cash payments from a patient only after the requirements of sections 8.2.a., 8.2.b. and 8.2.c. herein, have been fulfilled and documented.

WV Code §16-5Y-5(e) states, "Prior to directly billing a patient for any medication-assisted treatment, a medication-assisted treatment program must receive either a rejection of prior authorization, rejection of a submitted claim, or a written denial from a patient's insurer or West Virginia Medicaid denying coverage for such treatment: **Provided, That the Secretary may grant a variance from this requirement pursuant to section six of this article** [emphasis added]." This rule makes no reference to the payment variance option provided for in code and therefore further restricts the provisions of law beyond what the law provides. A rule may not be inconsistent with the underlying law. In this case the rule is presuming that every patient is either covered by Medicaid, private insurance or chooses to ignore the right, for whatever reason, to be directly billed for the services extended.

Ohio Valley Physicians treats any number of patients who receive employer-sponsored insurance coverage. These patients understandably may prefer to pay for substance abuse treatment services out of pocket so as not to be labeled by an employer and perhaps even the community. Therefore, the variance option provided for in code is

critical for some patients of Ohio Valley Physicians and is worthy of being reiterated in rule. Without this provision, the practical effect is likely to drive some patients out of treatment or, in other instances, cause them to seek treatment in distant locations outside the local area of their residence in order to avoid adverse notoriety they would hope to avoid. This is particularly true in border regions of our state where patients may choose to seek treatment in adjoining states and reduce the market opportunities for West Virginia clinics needed to sustain a sufficient patient population for not only medication-assisted treatment, but for other healthcare services as well.

8.3 Each OBMAT program facility shall have:

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

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

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

8.3.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;

8.3.e. Sanitary, secure and private dosing areas, if applicable;

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

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

Several of the provisions contained in subsection 8.3 either do not apply to the treatment offered by Ohio Valley Physicians or are difficult to determine. First, the language in 8.3.c appears to be grossly outdated as it fails to recognize the prolific use of electronic medical records. Next, 8.3.d requires the OMBAT program to have a private office or area for counseling. As mentioned previously, both the Medication-Assisted Treatment Program Licensing Act as well as the proposed OBMAT rule allow for the referral of counseling services. Therefore, Ohio Valley Physicians should not be required to have private counseling space on site.

Second, while Methadone may require daily on-site dispensing, the types of treatment provided by Ohio Valley Physicians do not. In fact, as already demonstrated, several provisions in the rule referring to the dispensing of medications have apparently been lifted from Methadone regulations and do not apply to OBMAT programs. OBMAT programs do not store medications on site because they do not dispense medications, nor do they require the same level of oversight as Methadone clinics. Therefore the provisions of 8.3.e do not apply in instances in which the office based treatment is distinguishable from those instances in which daily on-site dispensing occur.

As to 8.3.f and 8.3.g, sufficient restrooms and adequate parking are undefined subjective requirements. How many restrooms are sufficient and how many parking spaces are adequate? Frankly, it is all relative to the patient load, scheduling and local logistics in terms of parking garages or parking lots in the vicinity should the office facility lot become full for some reason. Once again, this would seem to be a rule directed at sites where daily dispensing occurs rather than an office based facility such as those operated by Ohio Valley Physicians. In some jurisdictions, local zoning ordinances dictate required parking, and local public health ordinances would address bathroom requirements. In those cases subdivisions 8.3.f and 8.3.g are redundant and potentially conflictive with local zoning and public health laws in local jurisdictions.

8.6. Community Relations.

This rule appears to be written based on a presumption that everyone seeking any type of treatment with Ohio Valley Physicians must be incapable of controlling him or herself in public. Requiring a physician's office to develop a policy to prevent disorderly conduct, harassment and loitering is frankly offensive to legitimate physician operated clinics. While it may be a legitimate concern to "pill mill" operations which should be and need to be eliminated under existing civil and criminal law, it is not a legitimate concern in the case of much needed responsible medication-assisted addiction treatment clinics.

Further, legitimate OBMAT facilities are not empowered under the law to protect communities from undesirable behavior by those who avail themselves of what service they have to offer. If one were to accept the logic presupposed by the rule, physicians who treat mental health disorders, such as bipolar disorder, schizophrenia and others, would be required to develop a plan to ensure the residents of a community in which the physician's office/clinic is located are not disturbed by the actions of their patients. The very fact that OBMAT clinics are dealing with patients who are addicted to drugs, illegal or otherwise, tells one that such patients are likely to be problematic in society until they achieve some level of sobriety. Requiring the medical profession to be responsible to the community for actions engaged in by a drug addict is not reasonable.

This section of the rule causes the OBMAT facility principles to function in the role of community protector and vigilante for which they have no authority to act. It imposes an obligation which extends far beyond the boundaries of the facility to regulate and govern the lives of individuals for which they have provided treatment. It exposes them to extreme civil liabilities and huge risks that are not manageable.

Instead of imposing subjective and likely unenforceable regulations on responsible members of the medication-assisted treatment health care community, perhaps attention should be directed to the enforcement of existing laws pertaining to loitering, harassment and the like. There can be no policy enforceable by a physician directed clinic to prevent a patient from re-entering the public domain and engaging in undesirable or illegal conduct – whether that be loitering or merely confronting other members of the public in what subjectively might be determined to be harassment.

8.7. Emergency Preparedness. -- The program's emergency preparedness plan shall include, but not be limited to, the provision of the continuation of medication-assisted treatment in the event of an emergency or natural disaster.

This provision is yet another example of trying to force Methadone regulations on OBMAT programs. Again, OBMATs do not dispense medications; medical professionals simply write the prescription deemed medically necessary to treat the patient and then the patient has the prescription filled at the pharmacy of his or her choice. There is no

daily dosing at the OBMAT site and therefore this provision is not applicable and should be stricken.

9.6.a. Provide 24 hour, seven day-per-week access to designated program staff, as described in section 8.1.c.2., so that patient emergencies may be immediately addressed and dosage levels verified

The requirement to maintain 7 day-per-week access to “designated” program staff for an OBMAT program is both costly and unnecessary. It has a major impact on the business model of the physician based practice. The physician based treatment regimen is based on appointments scheduled by patients. It is not a circumstance of daily dispensing of Methadone as this provision in rule would seem to imply to be the case. Verification of dosage levels is dictated by that which was prescribed previously in the timeline of patient care.

§69-12-12. Waivers and Variances.

There are two specific variances addressed in the Medication-Assisted Treatment Program Licensing Act which are not referenced in this rule. They are as follows:

§16-5Y-5(e) The medication-assisted treatment program shall be eligible for, and not prohibited from, enrollment with West Virginia Medicaid and other private insurance. Prior to directly billing a patient for any medication-assisted treatment, a medication-assisted treatment program must receive either a rejection of prior authorization, rejection of a submitted claim, or a written denial from a patient’s insurer or West Virginia Medicaid denying coverage for such treatment: Provided, That the Secretary may grant a variance from this requirement pursuant to section six of this article. The program shall also document whether a patient has no insurance. At the option of the medication-assisted treatment program, treatment may commence prior to billing.

§16-5Y-6(c) Medication-assisted treatment programs shall not be located within one-half mile of a public or private licensed day care center or public or private K-12 school.

Existing medication-assisted treatment programs, including both opioid treatment programs and office based medication-assisted treatment programs that are located within one-half mile of a public or private licensed day care center or public or private K-12 school, shall be granted a variance, provided that the facility demonstrates adequate patient population controls and that it may otherwise meet the requirements of this article and the rules promulgated pursuant to this article.

It is the request of Ohio Valley Physicians that these specific variances are at the very least referenced in the Waivers and Variances section of this rule. Otherwise, the rule makes another attempt at intrusion on the authority of the legislature by an executive branch agency by limiting implementation in rule of the express provisions of law legislated by the legislature and signed into law by the governor.

13.1.c. A report of an inspection or investigation made public shall also state whether a plan of correction has been submitted to or approved by the secretary.

Perhaps a better way of stating 13.1.c would be: “A report of an inspection or investigation, whether initiated by the secretary or pursuant to what is determined to be a prima facie violation of statute or rule, may be made public and shall also state whether a plan of correction has been submitted to or approved by the secretary.” In the event a spurious complaint is made against an OBMAT program which ultimately proves to be false or even maliciously cast, it would be an injustice to the program to make said complaint public if the complaint is found to be unsubstantiated. The mere accusation without some level of merit has the potential to harm the reputation of a respectable facility and bring harm to a program achieving success in the battle to arrest drug addiction in West Virginia. Caution needs to be observed and provisions made in the language of the rule to protect the essential element of client confidentiality.

13.2. Statistical Reports and Records.

While Ohio Valley Physicians will gladly submit the statistical information requested in 13.2 to the secretary for agency review and compilation, due to the nature of the information, we must ask that any reports generated by Ohio Valley Physicians containing these statistics not be available for public review other than in the aggregate of such information reported by all OBMAT programs. Otherwise, such information as reported by individual OBMAT programs may involve disclosure of proprietary competitive business information. It is therefore requested that a provision be added clarifying that the statistical reports and records referenced in subsection 13.2 will not be available to the public.

13.3. Incident Reporting and Adverse Events.

13.3.a. Each OBMAT program shall develop and implement policies and procedures for comprehensively documenting, investigating, taking corrective action and tracking instances of adverse events or incidents.

13.3.b Adverse events or incidents are defined as an event which may involve:

In terms of the provisions of 13.3.a and 13.3.b, it would seem prudent to alter the language of 13.3.b slightly to impose a more realistic duty on the OBMAT program. It would be a more manageable scenario for all if it read as follows: “Adverse events or incidents are defined as an event known to the OBMAT medical director which may involve.” Otherwise many of the items set forth in items 13.3.b.1, 2 and 3 and those items set forth in 13.3.c may be items never known to the OBMAT program. For instance, how would the program know whether “harm to family members or others from ingesting a patient’s medication” had occurred or by what means (theft for example) a patient’s medication had become possessed by a third party. Similarly, the rule as written would seem to impose an obligation on the OBMAT program to know if there was an incident in which there was a “potentially lethal patient suicide attempt.” If the suicide attempt occurred in a remote location and was never reported to the

OBMAT program, there is no way the program should be accountable for reporting such as it would have no way of knowing. Additionally, the likelihood of an incident to cause community concern is impossible to determine and difficult to report. How would one know and how could one be held accountable under the rule of law in such a circumstance? The list of events and incidents should be reviewed to better determine what an OBMAT program can realistically be responsible for documenting and revisions should be made to restrict the obligation of reporting as to those matters for which the program has actual knowledge. Once again caution should be observed to avoid violations of patient confidentiality.

13.3.f. Within seven days of an incident or adverse event, the program shall file a report with the state oversight agency on the incident or adverse event consisting of the following:

13.3.f.1. The action or actions implemented to prevent the reoccurrence of the incident or adverse event;

13.3.f.2. The time frames for the action or actions to be implemented;

13.3.f.3. The person or persons designated to implement and monitor the action or actions; and

13.3.f.4. The strategies for the measurements of effectiveness to be established

To the extent this is a self-reporting of facts and circumstances which may possibly involve illegalities (incidents or adverse events), one must be extremely careful. In addition to likely compromising patient confidentiality or perhaps reporting alleged criminal conduct, great risk of liability is a potential unintended consequence on OBMAT programs and perhaps others.

20.21.a. OBMAT programs shall accept patients transferring from another OBMAT program within the state of West Virginia, if:

20.21.a.1. The OBMAT program accepting a patient voluntarily transferring from another OBMAT program shall provide documentation that the patient's medical

record and reasons for the transfer was sought from the patient's previous OBMAT program; and

20.21.a.2. The patient is in compliance with readmission policies for patients who have been administratively detoxified.

Requiring an OBMAT program to treat a patient is not good policy, regardless of the requirements that the patient meets. Not having the option to refuse a particular patient is potentially harmful to the OBMAT program to which transfer is being made. It is potentially harmful on various levels. Medical care providers may not be forced to treat patients unless in an emergency situation. There may be any number of reasons that a provider would not want to accept a patient, including a preexisting relationship which failed for whatever reason, distrust of the patient by the program staff, patient's lack of insurance and/or inability to pay for service, patient's history of criminal activity or violence, which makes them unsuitable to co-exist with others in the program setting. It is strongly suggested that the word "shall" in 20.21.a. be stricken and replaced with the word "may."

21.2. When practicable, the OBMAT program shall obtain a written consent for release of information from the patient in order to check the records of every OBMAT program within 100 miles of the program site so as to ensure that the patient is not currently enrolled in those programs as well. The request for information may be made by telephone, fax or e-mail. The release of information shall state that only prior admissions may be the subject of inquiry, not contacts without admission. The OBMAT program shall protect patient confidentiality at all times and with all procedures used in acquiring medical or health information.

It is nearly impossible for a medical services provider to check the records of every OBMAT program within a 100 mile radius, as that provider is unlikely to even know of the existence of any and all OBMAT programs. This is particularly true of programs operating on the state's borders. By way of example, from Morgantown, WV to Pittsburgh, PA the distance is only 75.1 miles with any number of Pittsburgh suburbs

in between. From Parkersburg, WV to the edge of Columbus, Ohio the distance is nearly 100 miles with various and sundry communities in between. From Charles Town, WV to Baltimore, MD the distance is 75.7 miles with significant sized communities such as Frederick, MD, Hagerstown, MD, Cumberland MD and Leesburg, VA even closer. From Charles Town to Washington, DC, the distance is only 63.3 miles and the densely populated area of northern Virginia in between. From Lewisburg, WV to Roanoke, VA the distance is only 86.5 miles. The capacity for an OBMAT program to begin to know where other treatment programs are operating is an unrealistic expectation.

As an alternative and more meaningful information resource, it is recommended that the program be required to access the Controlled Substance Monitoring Database as a means of determining if the patient is receiving substance abuse treatment medications from another prescriber.

25.1. Each OBMAT program shall provide adequate medical, counseling, vocational, educational, recovery and other assessment and treatment services. These services must be available onsite at the facility or on a referral basis to outside providers and the medical director at an OBMAT program must be able to document that these services are fully and reasonably available to patients and comply with all federal and state laws, rules and regulations.

While Methadone clinics may be required to provide supportive services, physicians' offices and medical clinics that also provide medication-assisted treatment do not have the proper resources to provide vocational and educational services, nor would any health payer reimburse for these services. Unlike Methadone clinics, such services are out of the ordinary for OBMAT program practice standards. It is therefore requested that the words "educational" and "vocational" be stricken from this subsection.

25.11. Services provided by an OBMAT program should adhere to recovery initiatives promoted by federal and state laws, rules and regulations and the protocols and guidelines of approved authorities. Recovery initiatives include assistance in

overcoming or managing a patient's substance use disorder or other diseases;
encouraging a patient to live in a physically and emotionally healthy manner;
ensuring that the patient lives in a stable and safe place; engaging the patient in
meaningful daily activities, such as job, school, volunteerism, family caretaking or
creative endeavors; and assisting the patient in obtaining the independence, income
and resources to participate in society and in developing relationships and supportive
social networks.

Much like the previous comment, Ohio Valley Physicians is not equipped to ensure the safety and stability of a patient's home, engage in a patient's daily activities or assist the patient in obtaining income, nor are most counseling services. In fact, these recovery initiatives may even create unrealizable expectations in our state's current economy where even the most prime candidates are unable to achieve independence, income and resources to participate in society. As an alternative to requiring such extensive immersion into a patient's personal life, which is unrealistic in an OBMAT program, it is instead recommended that that an active relapse prevention plan be required that would address achievable goals, support structure, etc.

26.7. The clinical staff caseload ratio as defined in section 7.5.c. shall:

26.7.a. Reflect an appropriate clinical mix of gender, race and ethnicity
representative of the population served

This provision of rule demonstrates a significant naiveté in the availability of providers to West Virginia communities and those who narrowly work in the capacity of medication-assisted addiction treatment. West Virginia does not have the luxury of coordinating its providers of clinical care in a manner that reflects gender, race and ethnicity. The number of medical providers and counselors that treat substance abuse disorders is already seriously low and issues of access to care for those suffering from addiction have been fully demonstrated. To place requirements on the gender, race and ethnicity of those professionals is not only alarming, but it would restrict access so

severely that it would be a tremendous disservice to the treatment providers and patients alike. It is recommended that 26.7.a be stricken in its entirety.

28.1. Within 30 days after admission, or when the patient is stable and able to fully participate, the program shall complete a physical and biopsychosocial evaluation, which shall be used to develop the long-term individualized treatment plan of care. The physical and biopsychosocial evaluations shall integrate information obtained in all treatment of the patient at the MAT program.

This subsection seems inconsistent with current code as well as another section of this rule. While this subsection requires a biopsychosocial exam within 30 days after admission, §16-5Y(m)(5) states:

“An alcohol and drug abuse counselor, an advanced alcohol and drug abuse counselor or other qualified counselor, psychiatrist, psychologist or social worker shall perform a biopsychosocial assessment, including, but not limited to, a mental status examination of a patient on the same day or no more than seven days prior to the day that the physician initially prescribes, dispenses or administers a medication-assisted treatment medication . . .”

and section 25.3 of this OBMAT rule states:

“Each OBMAT program shall require every patient to undergo a complete, fully documented biopsychosocial assessment by a program counselor before admission to the OBMAT program. The full biopsychosocial assessment shall be completed at the time of admission and prior to the first dose of medication-assisted treatment medication.”

Were one to follow the relaxed time period in 28.1, one would be in violation of the underlying statute. Regardless of the timeline that is proposed by the agency rule, clarity and consistency as to when the initial biopsychosocial examination should take place is warranted.

29.7. Each MAT program shall provide opportunities for family involvement in the therapy provided to each patient and document such involvement in the individualized treatment plans of care.

We are in complete agreement that family involvement can be an important part of the treatment process and the opportunity for such should indeed be provided if appropriate. However, sometimes one's own family member/s do not represent the positive support system that is desirable in therapy and can retard the progress otherwise being made with the patient. Sometimes, family members may be part of a similar culture which has produced the patient suffering from addiction. In other circumstances, "each patient" as provided for in the agency proposed rule, may not have family available for purposes of being involved. Therefore, we request that language be added to this subsection which provides flexibility for such circumstances. A modification in the language used in 29.7 could easily accommodate this circumstance by simply beginning the section with the words "Where appropriate" prior to the word "Each" at the start of the sentence in 29.7.

30.3. Patients with two or more unsuccessful detoxification episodes within a 12-month period must be assessed by the OBMAT program physician for other forms of treatment. A program shall not admit a patient for more than two detoxification treatment episodes in one year. One year of physiologic dependence is not required for detoxification treatment although documentation of current dependency is required.

This could cause conflictive demands on OBMAT programs where a program is required under other provisions of the rule to accept patients transferring from another program. Language should be modified in this subsection to clarify how the impact of two or more detoxification episodes would affect patients transferring from one OBMAT program to another.

§69-12-30. Detoxification Program.

There are several references in this section, including entire subsections, to short-term and long-term detoxification treatment services. These terms and services apply to Methadone treatment programs only and are in no way a part of office-based medication-assisted treatment, as OMBAT consists of prescription treatments, not daily supervised doses. It is therefore requested that any mention of long-term and short-term detoxification treatment services be stricken, including subsections 30.11 and 30.12 in their entirety.

33.2.d.1. A patient receiving medication-assisted treatment medication maintenance services must at least one random drug screen per month during the first year of treatment and random drug screens quarterly thereafter.

Random drug screening is indeed an important component of any OBMAT program, as it serves as an accountability measure by detecting patient relapse and also helps to deter further drug use by patients.

However, it is important to recognize when a patient is selected for a random screening, he or she must call off work or cancel any other prior obligations in order to appear for the testing, as failure to appear would result in an automatic failure. It is for this reason that random monthly testing is considered by many professionals as overly burdensome for patients; requiring them to miss work or other engagements with little notice on a monthly basis could seriously jeopardize employer and other professional relations. Though it is recognized that requiring patients to cancel prior obligations for random testing is a necessary part of an OBMAT program to ensure compliance, requiring such on a quarterly rather than a monthly basis puts the patient at much less risk of damaging professional and perhaps even familial relationships.

Additionally, it is a common held belief that random monthly drug testing is, in fact, not random at all as it occurs on too regular a basis.

It is therefore recommended that 33.2.d.1 be amended to read, "A patient receiving medication-assisted treatment maintenance services must have at least two

drug screens per month and a random drug screen each quarter during the first year of treatment with random drug screens quarterly thereafter.” This language would still ensure a patient is being tested regularly on a bimonthly basis while still implementing random testing on a more patient-friendly quarterly basis.

The challenge for this rule is to balance regulation in a manner that does not deter the development of office based medication-assisted treatment of addiction. The addiction problem in West Virginia is so horrific that more rather than less treatment options are needed. The combined elements of counseling and medication as components of the treatment are exactly what are warranted. Preventing that from occurring by imposing a set of regulations which are, in many ways, non-germane to the circumstances of an office based medication-assisted treatment program is worrisome and does nothing to achieve the purposes of SB 454 in regard to office-based treatment programs. Should there be a desire on the part of the agency or the Legislative Rulemaking Review Committee to reinvent the rule to better accommodate the realities of office based medication-assisted programs, as the holder of a CARF Accreditation as an integrated behavioral health/primary care provider actively engaged in an obviously successful office based treatment model, Ohio Valley Physicians is prepared and willing to work collaboratively with agency officials, legislators, legislative staffers to do so.

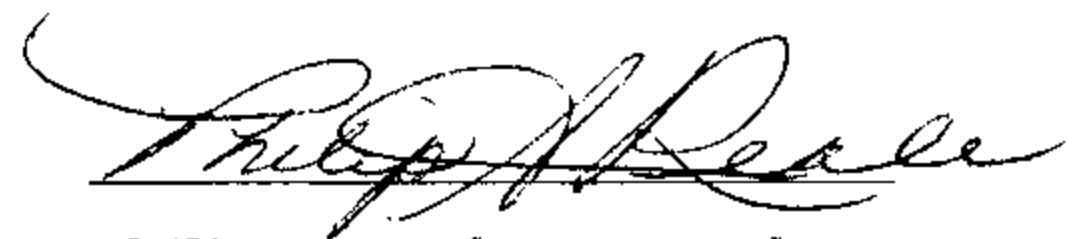
This concludes the comments submitted by Ohio Valley Physicians. Ohio Valley Physicians very much appreciates the attention of agency officials and others to the comments herein made. While it may not be readily apparent, Ohio Valley Physicians appreciates the immense effort required in drafting comprehensive registration and licensing requirements of first impression based on the recently enacted SB 454. It is fervently hoped that these comments provide some insight into the practical aspects of providing office-based medication-assisted treatment. Most importantly, Ohio Valley Physicians and its representatives appreciate the opportunity not only to provide input at this juncture, but also to work with the agency going forward to perfect the proposed rule and set the standard of care in terms of addressing the absolute need for West Virginia to proceed down the path of improved quality care for persons needing office-based medication-assisted treatment. The need for such is regrettably manifested

throughout the state and it requires dedication and commitment from the provider community as well as the general population to ease the burden this problem imposes on the entire state.

Respectfully Submitted,

Ohio Valley Physicians, Inc.

By:

A handwritten signature in cursive script, reading "Philip A. Reale". The signature is written in black ink and is positioned above the printed name.

Philip A. Reale, Counsel

State Bar I.D. #3029

Archived: Wednesday, August 10, 2016 6:12:13 PM

From: Lawson, Kathy M

Sent: Sunday, August 07, 2016 8:28:34 PM

To: Rutherford, Jennifer A

Subject: Fwd: Comment on SB 454

Importance: Normal

One of four coming your way.

Kathy Lawson
Inspector General
Department of Health and
Human Resources

Begin forwarded message:

From: Cameron Duffy <cduffymd@gmail.com>

Date: August 7, 2016 at 8:11:03 AM EDT

To: Kathy.M.Lawson@wv.gov

Subject: Comment on SB 454

Dear Ms. Lawson,

I treat opioid dependency with MAT (medication assisted treatment) in an outpatient setting and have been doing so for 7 years. I am also the Health Officer for the Berkeley County Health Department. I could spend hours dissecting the legislation related to SB454, but I really cannot afford the time to do so. What I will say is that this bill will dramatically reduce the availability of treatment for opioid dependence in our state and will likely result in ever more overdose deaths. I am now strongly considering relocating my opioid dependency treatment practice to another state because of this bill.

At a time when we should be making efforts to have more physicians treat the disease of opioid dependency, this bill will cause physicians to run from it. Here is an excerpt from AMA Morning Rounds.

"AMA chairwoman urges insurers to expand coverage for opioid addiction Patrice A. Harris, MD, chairwoman of the American Medical Association, writes in a letter to the editor of the Hartford (CT) Courant (8/1) that the AMA concurs "with Aetna medical officer Dr. Mark Friedlander that we need to increase access to medication-assisted treatment for patients with substance use disorders." She says the AMA is also urging "Aetna, Cigna and all other payers in Connecticut to remove barriers to evidence-based care, including limits on physical therapy, cognitive behavioral therapy, psychiatric care and other multimodal therapies that may be appropriate." Harris adds that in order to effectively combat the opioid epidemic, "physicians must continue to play an active role in treating our patients using evidence-based care, and that also means insurance policies must provide our patients with the benefits, coverage and access necessary for that care."

SB454 does nothing to increase access to MAT, it will only do the opposite. This bill will only further West Virginia's position as the leader of opioid overdose deaths in the nation. It is sad that our Governor and Legislature have been persuaded into thinking this bill will do otherwise.

Sincerely,

Cameron Duffy, MD, MBA



Rachel Sowards, MD Medical Director
808 B Street, St Albans, WV 25177
P: 304-729-8007 F: 304-729-8030

August 7, 2016

M. Katherine Lawson, Inspector General
WV DHHR, Office of Inspector General
State Capitol Complex
Building 6, Room 817-B
Charleston, WV 25305

RE: 69 CSR 12 Medication-Assisted Treatment – Office-Based Medication-Assisted Treatment

Dear. Ms. Lawson:

I am dually trained in psychiatry and internal medicine and I am board certified in both specialties as well as the American Board of Addiction Medicine. In 2011, I started prescribing Suboxone to a small number of patients at a Federally Qualified Medical Clinic. In the following years, we developed a program that included on-site counseling, primary care, psychiatric care, etc. I am currently the Medical Director at Links, which is an outpatient treatment facility for addiction affiliated with Psimed. One of the treatments we provide is buprenorphine, so the new rule governing office based medication assisted treatment will affect our clinic and patients.

I have reviewed comments that will be submitted by some of my colleagues. I agree with many of these, but cannot support them all. Therefore, I have made my own suggestions as follows:

- 1) It would be almost impossible for the smallest programs to completely follow the rules. Most of us believe that these should be able to obtain a waiver to continue to treat patients as per the Comprehensive Addiction and Recovery Act but with special allowances. Having experience in such a setting, I do not believe that a solo practitioner with limited resources would be able to provide adequate care to more than 30 patients. Therefore, if such a physician asks for a waiver due to size and resources, I believe the number of patients they maintain should be around 30.
- 2) 6.1.c. The same program should not have to register separately for two locations.
- 3) There is no reason for the medical director to be on site 75% of the time. Unlike an OTP, medication is not being dispensed. There are days where only counseling is taking place in our clinic.
- 4) 8.5 and -8.6 – The Medical Director and Program Coordinator should be well equipped to respond to community concerns as required. The idea that “policies and procedures for soliciting patient and community ideas about medication-assisted treatment” would not be beneficial to our patients. The community should be educated on addiction by medically trained professionals, not invited to give non-medical opinions as to how

addiction should be treated. This could reinforce the negative stigma associated with treatment and should be deleted.

- 5) 13.2 – Statistical reporting in such detail is usually required by a grant-supported facility such as an FQHC, not a private clinic. The detail in this section is excessive, as is the frequency. This information (why the patient is discharged, time in treatment, etc.) is available in the patient charting if needed. A non-government clinic such as most OBMAT facilities do not participate in research, thus such detailed data is not usually kept separately. Further, reporting the information as outlined here would be a breach of patient confidentiality.
- 6) 15.1.d.2.A- While the patient should be maintained on the lowest EFFECTIVE dose, there is no evidence that the strength of a MAINTENANCE dosage should decrease over time. It is, by definition, prolonged treatment. While the dosage often does decrease over time, each person's dosage must be individualized and should follow the current standard of care.
- 7) 18 – Patients taking part in OBMAT programs should be subject to the standard of care that applies to other practices. They should be informed of their rights and responsibilities and the grievance process of the program. These should be reviewed and signed and they should have a copy. Having it displayed in patient area is not expected in other doctor's offices and seems like overkill, and may even encourage litigiousness. 18.1.i. – while a program should make referral to appropriate care when a person is denied admission, that care may not be another OBMAT. Usually, if they are denied, it is because the provider feels they need a more intense level of care or are not a good candidate for OBMAT. Otherwise, they would not have been denied. Rather than putting the reason for denial in writing, it would be more beneficial to put the recommendation for appropriate treatment in writing. Further, there is absolutely no indication to give them a written "acceptance" letter or a copy of their initial assessment. This is never expected in any other physician's office.
- 7) 19- I agree that a physical exam at a initial assessment is appropriate to look for complications of drug use that could be acutely harmful or impact treatment. It does not usually need to be repeated every 90 days. Each patient should have a primary care physician for routine physical exams. There is also no need for a full biopsychosocial evaluation be repeated every 90 days. With the frequent medical and counseling sessions, any pertinent biopsychosocial changes will be noted in the progress notes.
- 8) 22 – Most of us routinely check a board of pharmacy report on admission, and at least every three months. This may be done more often if there is reason to believe that a patient is filling unapproved controlled medications. It is usually not necessary to check it more often. (The rule currently requires it after 30 days of treatment and after any positive test).
- 9) 25 - See #8 above. Also, this section says the biopsychosocial assessment must be completed prior to admission, whereas 19.7.d says it has to be within 30 days of admission. We need clarification as to when this actually must be completed.
- 10) 27- There is no need for the detailed post-admission assessment unless the initial assessment is somehow not complete at admission and must be continued. The information required in the post-admission assessment is usually gathered in the pre-admission assessment.
- 11) 29 - The patient should be presented with treatment options that include maintenance vs medically supervised withdrawal at the beginning of treatment. This discussion should include the pro's and con's of each option. Every time the patient's progress is evaluated and treatment plan updated there should be consideration as to whether the

plan is working or should be changed. Research shows a high risk of relapse after detox and that risk of relapse decreases with increasing length of treatment with MAT. Therefore, the patient should not routinely be pushed in the direction of a shorter medically-supervised withdrawal. The current wording suggests they shall be presented with option of participating in other treatments every quarter and sign a statement. This seems to insinuate that withdrawal is the preferred method of treatment.

- 12) 30 - Much of this section seems to apply to methadone treatment (Discussion of unsupervised and take home doses) and has no place in this ruling. There is no evidence suggesting that maintenance treatment should be discontinued in a set period of time, yet the ruling suggests it should be done in two years. The patient should be maintained on the lowest EFFECTIVE dose. Therefore, there should be no need for a provider to explain why they are still on medication past two years. However, it is reasonable to expect that there has been an attempt on the part of the treatment team to wean to the lowest effective dose for that individual. It is not unusual for cash-only clinics to put a patient on a high dose on admission and never try to decrease the dosage. I agree that this needs to change, but expecting everyone to be off in two years is not the answer. It may be useful for an explanation to be required if the patient is still on the same exact dosage after the initial two years of treatment.
- 13) 32.4 – There is no need to perform a new complete biopsychosocial assessment on a patient who is readmitted within 30 days. It would also not be likely that an insurance company would want to reimburse for a second such assessment within a month.
- 14) 33 - It makes sense that random screens as well as observed urine screens are useful in deterring attempts at altering urine or timing use where it would not be detected. However, expecting a random each month for each patient and expecting each urine to be observed seems excessive, as most of us are already checking the urine on their routine visit. Checking a portion of the patients randomly each month and observing the random screens (as well as if there is any suspicion of misuse) should be sufficient. The suggestion that patients be discharged or withdrawn for over 3 abnormal screens in 6 months needs dropped. That is a judgement call that should be made by the treatment team based on many factors including the level of danger in the combination of unapproved chemicals (such as mixing sedatives with buprenorphine), the likelihood of diversion with a negative urine, and the other options that are available for the individual.
- 15) 34- It is not reasonable to expect an OBMAT program to provide maternal, physical and dietary care during pregnancy. Such care should be provided by an obstetrician. Most OBMAT physicians do not have that expertise. Similarly, they should not be expected to provide parenting skills. That should be available through referral.
- 16) There are numerous references throughout the document regarding take-home doses and other aspects of methadone treatment that have nothing to do with OBMAT programs. The references are often tied to a rule that does not apply with OBMAT treatment and each should be removed.

These are the parts of the ruling that I feel need attention. There are several parts that some of my colleagues will argue (number of patients per therapist, allowing only a screening urine cup, no minimum number of counseling sessions) that I believe should stay as they are.

Unfortunately, there are providers who are more interested with maximizing their own personal gain than in helping these patients continue toward recovery. I do feel strongly that each patient must be approached as an individual, and though this rule should be a guideline, there will be those whose life circumstances require exceptions. These types of decisions should still be up

to the treatment team and there should not be any punishment when the reasons for such exceptions are well-documented.

Thank you for considering my thoughts as you clarify these points, and please contact me if I can be of any help in the finalization of the ruling. I assure you that I have the well-being of this vulnerable group of patients in mind while writing this letter.

Sincerely,

A handwritten signature in black ink, appearing to read "R Sowards MD". The signature is fluid and cursive, with the letters "R", "S", and "M" being particularly prominent.

Rachel Sowards, MD

DABPN, DABIM, DABAM, AAMRO



August 5, 2016

M. Katherine Lawson, Inspector General
WV DHHR, Office of Inspector General
State Capitol Complex
Building 6, Room 817-B
Charleston, WV 25305

RE: 69 CSR 12 Medication-Assisted Treatment – Office-Based Medication-Assisted Treatment

Dear, Ms. Lawson:

The undersigned organizations, representing more than 1,200 West Virginia physicians and more than 3,900 physicians and allied health professionals across the nation who specialize in the treatment of addiction, write to provide comment on the Proposed Rule related to Medication-Assisted Treatment – Office-Based Medication-Assisted Treatment (OBMAT). We appreciate the extensive thought and effort that has already been put into the development of this proposed rule, and we are grateful for the opportunity to provide formal public comment.

We understand the purpose of the rule is to ensure that all West Virginia OBMAT programs conform to a common set of minimum standards and procedures to ensure the care, treatment, health, safety and welfare of their patients. We applaud this intent and share the Department of Health and Human Resource's concern for the quality of care offered to patients receiving OBMAT.

However, we are similarly concerned with ensuring continued access to evidence-based opioid addiction treatment in the office setting. The purpose of the Drug Addiction Treatment Act of 2000 (DATA 2000), which established the process for individual physicians to obtain a waiver to treat patients with addiction with FDA-approved Schedule III-V opioids in their office, was to improve treatment access and uptake by integrating addiction treatment into routine medical care. With the approval of the first buprenorphine product indicated for addiction treatment in 2002, patients could potentially access medication-assisted treatment from their personal doctor, rather than having to go to a separate opioid treatment program (OTP). Many physicians who offer this treatment do not run "programs" or "clinics," but instead treat patients with addiction as part of their normal medical practice. By proposing to regulate this treatment service as if it were being offered by specialty facilities like OTPs, the Department risks driving physicians away from

offering medication-assisted treatment, reversing the intent of DATA 2000, and eliminating access to treatment for many West Virginians for whom it is life-saving.

In fact, we have already learned that two physicians, one who practices in Nitro, and the other in Huntington, who treat a combined total of 130 patients, have both decided to discontinue their OBMAT practices due to the anticipated challenges of complying with onerous new rules. In addition, we have heard that more than 50 other physicians in the state who provide OBMAT to more than 2,400 patients also could stop treating their patients with addiction disorders due to these untenable rules. According to the CDC, West Virginia has the highest rate of drug overdose deaths in the country, and deterring providers from offering life-saving treatment can only exacerbate the problem.

Indeed, we anticipate that this proposed rule, if finalized as such, will unduly burden all physicians who offer this service and serve as a strong disincentive to providing such care. Further, we believe these regulations would have a disproportionately negative impact on small and solo physician practices. At a time when West Virginia is grappling with an epidemic of opioid addiction and overdose deaths, and at a time when federal authorities and the medical community are striving to expand access to OBMAT, we urge the Department to revise the rule as detailed below so that its laudable endeavor to ensure quality does not inadvertently restrict access to life-saving treatment.

The following comments are made with the intention of trying to balance the legislative goal of ensuring appropriate accountability to the Secretary, with a public health goal of ensuring access to quality care. For that reason, the undersigned groups believe that it is imperative to make the rules clear, simple, and useful, while not making them so cumbersome that otherwise willing and qualified physicians would be discouraged from providing treatment to a very vulnerable patient population.

For each section named below, we have included a description of and background information about the issue, followed by suggested changes to the specific provisions of the section.

DETAILED COMMENTS

The proposed regulations for OBMAT set forth registration, reporting, and other requirements that far exceed the current Federal requirements for Opioid Treatment Programs (OTPs). OTPs, under Federal rules, are not subject to patient limits (as OBMAT providers will be), and are authorized to dispense methadone, a Schedule II controlled substance. The Federal Government has recently finalized regulations for OBMAT providers who are interested in treating between 100 and 275 patients. The new rule, effective August 8, 2016, will require applications to the Federal Government, who can approve, deny, not renew, or revoke the approval at any time. In addition, these OBMAT providers must agree to connect patients to certain services, and are subject to annual reporting requirements. These new rules are intended to provide accountability, help reduce diversion, and help ensure that patients receive adequate care. West Virginia may

want to consider a similar, staggered approach, so that physicians who treat very few patients in rural and other settings are not dissuaded due to burdensome requirements.

For example, the rules could stipulate that they only apply to practices with more than 30 patients. Programs with 30-100 patients could be subject to lower fees and less stringent requirements, or be exempt from some requirements. All programs, regardless of size, are required to abide by federal regulations.

The WV OBMAT regulations could also include conditions under which physicians could obtain a waiver from the requirements, as the WV Legislature approved in SB 454, §16-5Y-6(d). We propose that physicians meeting one or more of the criteria below be eligible for a waiver from these requirements.

§69-12-XX. Waivers and variances.

XX.1. Physicians may obtain a waiver from the requirements set forth in this chapter if they treat 30 or fewer of the patients in their practice with OBMAT.

XX.2. Qualified physicians may obtain a waiver from the requirements set forth in this chapter, regardless of the number of patients in their practice treated with OBMAT, up to the maximum allowed by law, so long as they hold a current WV medical license, a valid DEA registration number, and meet one or more of the following conditions:

XX.2.a. The physician holds a board certification in addiction psychiatry or addiction medicine from the American Board of Medical Specialties.

XX.2.b. The physician holds an addiction certification or board certification from the American Society of Addiction Medicine or the American Board of Addiction Medicine.

XX.2.c. The physician holds a board certification in addiction medicine from the American Osteopathic Association.

XX.3. Physicians may apply for and obtain waivers or variances from the requirements in this rule, for reasons other than those enumerated above, by making written application to the secretary, explaining the rationale for the request, and describing how the physician will maintain quality of care for his or her OBMAT patients if the waiver or variance is granted.

§69-12-2. Definitions.

We appreciate the effort to create separate and distinct rules for Opioid Treatment Programs (OTPs) and Office-Based Medication Assisted Treatment (OBMAT) programs because of the significant differences between the two types of treatment for patients suffering from Opioid Use Disorder. Because of those significant differences, however, we feel it is imperative to include a definition for medication-assisted treatment. The definition

below is based on the definition used by the Substance Abuse and Mental Health Services Administration (SAMSHA).

We recommend the following specific additions and changes (additions are indicated by underscore and deletions by strike-through):

2. xx - Office Based Medication Assisted Treatment (OBMAT)—Treatment that combines the use of FDA-approved medications with evidence-based behavioral therapies for patients with opioid use disorders.

2.31. Mental Health Professional -- A person licensed under chapter 30 of the West Virginia Code as a social worker, psychologist or professional counselor, or as a physician who specializes in psychiatry.

2.33. Opioid Drug -- Any substance or drug having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug or substance having such addiction-forming or addiction-sustaining liability including, but not limited to, buprenorphine, fentanyl, heroin, hydrocodone, hydromorphone, methadone, morphine, codeine, Oxycontin, oxycodone, oxymorphone, and other medications that block the transmission of pain messages to the brain any natural, semi-synthetic or synthetic drug that acts primarily through any opioid receptor in the central nervous system.

§69-12-6 Registration of OBMAT programs: Fees and Costs

In this section, the requirement for separate registrations for each practice location seems unnecessary. Some physicians practice OBMAT at more than one location, primarily due to space limitations. An OBMAT program could operate with the same administration and professionals in more than one location, and it seems redundant to require separate registrations for each one. We understand the purpose of a requirement for separate registrations for facilities that operate independently or are not located in reasonably close proximity, so we recommend that the Secretary should have discretion to determine when separate registrations are warranted.

In regard to fees, unreasonably high and indeterminate fees could seriously impede clinicians' interest in providing OBMAT. Finding physicians who are willing to provide services to this group can be challenging enough without requiring large or unspecified fees. For programs with a small number of patients, the fee could be reduced or waived until they attain a certain number of patients. In determining the amount of the fees, the adjustment for consumer price index and reliance on number of registrants, as well as the unknown cost of the requisite inspection, seems unprecedented. Generally, licensure fees are set at a fixed amount, and the cost should include any necessary inspections. Further, charging twice as much for a renewal as compared to an initial registration seems counterintuitive.

Given the above concerns, we recommend the following changes:

6.1.b. A registration is valid only for the ~~location and persons~~ program named and described in the application.

6.1.c. Each OBMAT program location shall be ~~registered separately, identified on the application, regardless of whether the program is operated under the same business name or management as another program.~~ The Secretary shall have discretion to determine whether a separate registration is required for a particular location, such as if the locations operate with a significant degree of independence.

6.2.a. The owner(s) of an OBMAT program shall submit an application for ~~an~~ a new OBMAT program registration to the secretary not less than 30 days and not more than 60 days prior to the anticipated initiation of services.

6.3.a. All applicants for an initial, provisional or renewed registration shall be accompanied by a non-refundable fee in the amount required by this rule. ~~The annual renewal fee is based upon the average daily total census of the program. In addition to the set fee, the annual renewal fee shall be adjusted on the first day of June of each year to correspond with increases in the consumer price index.~~ The base amounts for initial, provisional and renewal fees are as follows:

6.3.a.1. Initial registration fee – \$250;

6.3.a.2. Provisional registration fee – only for existing programs as of the effective date of this rule seeking an initial license – \$250; and

6.3.a.3. Renewal registration fee – ~~\$500 plus adjustment~~ \$250.

~~6.3.b. An OBMAT program shall pay for the cost of the initial inspection made by the secretary prior to issuance of a registration. The cost of the initial inspection of an OBMAT program is \$250 plus the cost of the inspection and shall be billed to the applicant by the secretary.~~

§69-12-7 Administrative Organization and Management of OBMAT Programs

The proposed requirement that every physician practice offering medication-assisted treatment employ a separate program administrator would be prohibitively costly for most physicians. We believe these staffing requirements are far too onerous and should be eliminated in the final rule. Moreover, the proposed requirements related to the program administrator's education and experience are too prescriptive and would severely limit the applicant pool if this requirement for a separate program administrator is retained in the final rule. Many physicians employ only an office manager who may or may not have a bachelor's degree and likely would not have the amount of specialized experience detailed in the proposed rule. We believe this requirement would be too difficult for most physician practices to meet and would be an unnecessary barrier to care.

The proposed requirement that the medical director shall practice a certain number of hours per week could prevent many offices from functioning. There is no clinical or

therapeutic reason for this requirement, and the DEA already provides regulatory guidance on this issue. It also would preclude the use of telemedicine or telepsychiatry, since the physician would not be “on site.” Telemedicine and telepsychiatry have been the conduit for successful treatment of many patients in our very rural state.

The proposed requirement that each practice assign a primary counselor to each patient and ensure that there be at least one counselor for every 50 patients in the “program” is also excessive. There is no evidence to support such an arbitrary ratioⁱ and it has even been eliminated from federal regulations for OTPs. Additionally, it is unrealistic to require physicians’ practices to be able to document training and supervision of counselors who are used on a referral basis. Instead, we believe it is reasonable for a physician to document and demonstrate the qualifications of the counseling staff used on a referral basis as defined in Senate bill 454. That is, we believe it is reasonable for the Department to require that physicians demonstrate they are referring patients to counselors who are either licensed psychiatrists; certified alcohol or drug counselors; certified advanced alcohol or drug counselors; master’s level counselors, psychologists, marriage and family therapists, or social workers; or a bachelor level counselor working under the direct supervision of an advanced alcohol and drug counselor. Such documentation of the physician’s referral to a qualified counselor should be considered satisfactory.

7.1. Each OBMAT program shall identify a ~~program administrator~~, medical director, and, if applicable, a program administrator, program physician(s), and counseling staff.

7.2.a. The administrator of an OBMAT program ideally shall have ~~at a minimum~~ a bachelor’s degree in an appropriate area of study and a minimum of four years of experience in the fields of substance use disorders, behavioral health or health care administration or a master’s degree in an appropriate professional area of study and a minimum of two years of experience in the fields of substance use disorders, behavioral health or health care administration; or eight years of experience in the fields of substance use disorders, behavioral health or health care administration.

7.3.e. The medical director shall ~~practice 75 percent of the hours in which the OBMAT program is operating each week in order to ensure regulatory compliance and~~ carry out those duties specifically assigned to the medical director. Nothing in this rule prohibits an OBMAT from designating co-medical directors.

7.3.f. Within 10 days after the withdrawal or termination of the medical director, the owner or owners of the program shall notify the secretary of the identity of another medical director for the program. During the interim, not to exceed 60 days, another licensed physician shall be present during all hours of operation, or immediately available by telephone or telemedicine, except in the event of an emergency or unforeseen event, and shall assume the duties of the medical director on a temporary basis until such time as a new medical director is identified and begins work at the program. The interim physician may be another owner of the program or a program physician employed by or associated with the program.

7.5.c. Each OBMAT program's policies and procedures shall ~~establish ratios of primary counselors to persons served that are adequate to allow sessions to occur as mandated and that will allow persons served access to a primary counselor, either on site or by referral, but there shall be at least one counselor for every 50 patients in the program.~~ demonstrate that patients are actively engaged in addiction therapy through regular group and/or individual sessions with a therapist that occur at least weekly during the first three months of treatment.

§69-12-8 Environment and Operation of Office-Based Opioid Treatment Programs.

We understand the law requires that, prior to directly billing a patient for any medication-assisted treatment, a physician's practice receive either a rejection of prior authorization, rejection of a submitted claim, or a written denial from a patient's insurer or West Virginia Medicaid denying coverage. However, we also understand the law gives the Secretary the authority to grant a waiver or variance from this requirement. We strongly support the granting of such waivers to solo practitioners and small group practices that do not have the infrastructure required to submit insurance claims. Further, we encourage the Secretary to grant a waiver from this requirement to practices that treat patients who want to maintain confidentiality of their addiction treatment from their employer or insurer.

Sections 69-12-8.5 and -8.6, which would require "programs" to develop and implement policies and procedures for infection control and community relations, seem unnecessary for OBMAT programs and more appropriate for OTPs. Such requirements not only further the stigmatization of patients with addiction, but amount to burdensome administrative paperwork requirements that do nothing to promote the quality of care offered by a practice. In fact, by devoting time and resources to documenting efforts to avoid community disruption and developing "policies and procedures for soliciting patient and community ideas about medication-assisted treatment," physicians would be spending less time providing care, counseling patients and ensuring that their practices are meeting recommended clinical quality standards. A medical practice should be abiding by nationally recognized clinical practice guidelines, not community ideas of what treatment should be. It should be attentive to its patients' concerns and needs rather than those of non-patients who may hold stigmatizing views of persons with addiction. We recommend striking this section of the proposed rule to minimize unnecessary administrative requirements that do not contribute to treatment quality and avoid giving official credence to non-medical opinions about addiction treatment.

8.1.c.1. ~~The program shall notify the individuals receiving medication-assisted treatment services in writing at least 30 days in advance of their intent to close on Sunday or permanently change service hours.~~ All individuals patients shall receive an orientation addressing policies and procedures, and this orientation shall be documented in the individual's patient's record prior to receiving medications; and

8.2. Payments for services rendered may be made either by West Virginia Medicaid, Medicare, private insurance, or by cash ~~as described in 8.2.d.~~

~~8.2.a. The OBMAT program shall be eligible for, and not prohibited from, enrollment with West Virginia Medicaid and other private insurance.~~

~~8.2.b. Prior to directly billing a patient for any opioid treatment, the OBMAT program must receive either a rejection of prior authorization, or rejection of a submitted claim or a written denial from a patient's insurer or West Virginia Medicaid denying coverage for such treatment.~~

8.2.e.a. The OBMAT program shall document in the patient's record any rejection of prior authorization, rejection of a submitted claim for written denial from a patient's insurer or West Virginia Medicaid denying coverage for opioid treatment. The OBMAT program shall also clearly document in the patient's record if the patient has no insurance or has voluntarily and with full knowledge of the financial obligations, including all treatment costs, requested a claim not be submitted to their insurer or West Virginia Medicaid. When any instance described in this section regarding direct billing and acceptance of cash payments from a patient occurs, the OBMAT program shall clearly document in the patient's record the rationale and medical necessity for acceptance into the program.

~~8.2.d.b.~~ The OBMAT program may directly bill and accept cash payments from a patient ~~only after~~ if the requirements of sections 8.2.a., 8.2.b. and 8.2.e. herein, have been fulfilled and documented, or if the secretary has granted a waiver of this requirement.

~~8.5. Infection Control.~~ [[Delete entire subsection.]]

~~8.6. Community Relations.~~ [[Delete entire subsection.]]

§69-12-9. Facility Construction and Renovations; Life Safety Policies and Procedures

The provisions of this section seem more pertinent to OTPs, and we recommend that the section be deleted in its entirety. Subsections 9.1. and 9.2. refer to construction of OBMAT facilities, which might apply to an OTP seeking to expand its practice but does not seem relevant for existing OBMAT programs. Subsection 9.5 pertains to facilities which dispense medications, which are classified as OTPs, and it does not apply to OBMAT programs. It would be unprecedented for the DHHR to require a private physician practice to submit architectural drawings for approval prior to construction or expansion of their practice.

~~9.1. Before extensive construction or renovation of an OBMAT program facility begins, the program shall submit to the secretary for approval a complete set of the plans for the project, which includes the drawings and specifications for the architectural, structural and mechanical design and work.~~

~~9.2. The secretary shall advise the program whether approval has been granted. In the event the plans for the project are not approved, the secretary shall set forth in writing the reasons for the disapproval and provide the program the opportunity to~~

~~correct any deficiencies. Extensive construction or renovation of a facility may not begin until the secretary has issued final approval of the plans.~~

~~9.5. Life Safety Policies and Procedures. [[Delete entire subsection.]]~~

§69-12-13. Reports and Records.

This entire section is problematic. It was not required under SB 454, which stated that reporting requirements only applied to providers who dispensed medications to patients, and therefore does not include OBMAT providers. OBMAT providers would not be able to comply with the onerous requirements in this section. Private clinics do not have the ability to track this kind of data with any credibility; the requirements are consistent with grant-supported, research-level data collection and are not feasible in private practice.

~~**§69-12-13. Reports and Records.** [[Delete entire section.]]~~

§69-12-15. Risk Management.

There is no evidence or justification for the statement in 15.1.d.2.A., and it is contrary to current standard of care. It should be deleted. In fact, the entire subsection 15.1.d is overly prescriptive and interferes with physicians' ability to practice unencumbered under their medical licenses. 15.1.b. covers the provisions in 15.1.d., so we recommend that the entire subsection 15.1.d could be deleted.

~~15.1.d.2.A. The strength of maintenance doses of medication-assisted treatment medications should decrease over time, as clinically indicated; and~~

§69-12-16. Medication Security, Storage, Administration and Documentation.

This section seems to apply to OTPs and not to OBMATs; in fact, 16.5 states "An OBMAT program and its physicians shall not dispense or administer medication-assisted treatment drugs on site." Since OBMATs do not dispense or administer medications on site, then the entire section is unnecessary and should be deleted.

~~**§69-12-16. Medication Security, Storage, Administration and Documentation.** [[Delete entire section.]]~~

§69-12-17. Continuous Quality Improvement Policies, Diversion Control Plan.

Much of the language in this section applies to OTPs but is not applicable to OBMAT programs (e.g., "take home doses"). Further, "national outcome studies" are only required for OTPs, not OBMATs, and they would be prohibitively expensive for OBMAT providers. We recommend that the section be deleted, except for the following provisions.

17.1. Each OBMAT program shall develop, implement and maintain current quality assurance and quality control plans that include provisions for:

17.1.a. Regular and continuous staff education;

17.1.e.b. A service delivery assessment which, at a minimum, shall evaluate appropriateness of the individualized treatment plan and services delivered, completeness of documentation in patients; records and quality of and participation in staff training programs, linkage to a utilization of primary care and other out-of-program services, and availability of services and medications for other conditions;

17.1.g.c. An ongoing assessment, measurement and monitoring of patient outcomes, treatment outcomes and the various processes including, but not limited to:

17.1.g.c.1. Reduction or elimination of the patient's use of illicit opioids, illicit drugs and the problematic use of licit drugs;

17.1.g.c.2. Reduction or elimination of associated criminal activities;

17.1.g.c.3. Reduction of the patient's behaviors contributing to the spread of infectious diseases;

17.1.g.c.4. Improvement of quality of life through the restoration of physical and behavioral health and functional status, including employment or volunteerism, as may be appropriate; and

~~17.4.2. An OBMAT program shall maintain a current "Diversion Control Plan" (DCP) as part of its quality assurance programs that contains specific measures to reduce the possibility of diversion of controlled substances from legitimate treatment use. The DCP shall assign specific responsibility to the medical and administrative staff of the OBMAT program for carrying out the diversion control measures and functions described in the DCP. Each OBMAT shall have a plan to manage medication diversion as part of its policy and procedures.~~

§69-12-18. Patient Rights.

This section includes psychiatric jargon ["patients who act out"] and provides grievance procedures that are not required in all physicians' offices. Such procedures in OBMAT programs should be subject to the standard of care that applies to general practices. Further, it is a physician's prerogative to refuse to accept patients, and a requirement to provide a "full explanation" goes beyond the appropriate standards of care to which physicians are already bound

18.1.i. To be given a copy of the initial assessment, written acceptance into the program; or, in the case of denial of admission, ~~a full explanation as to the basis of the denial, and~~ a referral to another OBMAT program based upon the results of the initial assessment;

18.1.n. To be entitled to protection from other ~~patients who act out~~ patients' disruptive actions or behavior. The program shall attempt to determine the cause of that behavior so that an appropriate referral to an alternative method of care can be made.

~~18.2. The OBMAT program shall have patient grievance procedures which shall be displayed in the patient care area 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. The procedures shall inform the patients of the following: conform to the standard of care for physician practices.~~

~~18.2.a. The right of a patient to express verbally or in writing his or her dissatisfaction with or complaints about treatment received;~~

~~18.2.b. The right of a patient to initiate grievance procedures without fear of reprisal;~~

~~18.2.c. The right of a patient to be informed of the grievance procedure in a manner that can be understood by the patient; and~~

~~18.2.d. The right of a patient to receive a decision in writing with the reasoning articulated.~~

§69-12-19. Patient Records.

This section is more pertinent to OPTs than OBMATs. There are references to physical examinations, which are not done in OBMATs unless clinically indicated. To require every patient to undergo these routinely would increase costs and serve no medical or therapeutic function. Further, “individualized treatment plans” are written for OTPs, and inpatient and day hospital psychiatric patients. OBMAT practitioners write clinical notes regarding treatment plans. “Detoxification treatment plans” are contained in federal OTP language and are not appropriate for OBMAT programs.

~~19.7.e. All physical and biopsychosocial assessments completed every 90 days if clinically indicated;~~

~~19.7.f. Medical reports including results of the physical examination biopsychosocial assessment; family medical history; review of systems; laboratory reports, including results of required toxicology screens; results obtained from the Controlled Substances Monitoring Program database; and progress notes, including documentation of current dose and other dosage data;~~

~~19.7.i. The initial and post-admission individualized treatment plans of care, and any amendments, reviews or changes to the plans; The clinical notes;~~

~~19.7.j. Documentation that the services listed in the individualized treatment plan of care are available and have been provided or offered;~~

~~19.7.k. A written report of the treatment process; factors considered in decisions impacting patient treatment, e.g., take-home medication privileges, changes in counseling sessions, changes in frequency of toxicology screens; results from the~~

~~Controlled Substances Monitoring Program database; documentation of whether the patient was offered or accepted a detoxification treatment plan option; and any other significant change in treatment, both positive and negative;~~

~~19.7.q. Consent forms, releases of information, prescription documentation, travel and employment; and~~

§69-12-20 Pre-Admission Assessment; Admission Criteria and Admission Process

We recommend including the American Society of Addiction Medicine's (ASAM) criteria as acceptable and preferred criteria to use for assessing a patient and determining the appropriate level of care. ASAM's treatment criteria provide separate placement criteria for adolescents and adults to create comprehensive and individualized treatment plans. Adolescent and adult treatment plans are developed through a multidimensional patient assessment over five broad levels of treatment – including outpatient treatment – that are based on the degree of direct medical management provided, the structure, safety and security provided and the intensity of treatment services provided.

20.2. Any individual seeking admittance to the OBMAT program shall undergo a pre-admission initial assessment in order to determine whether the person meets the criteria for admission to an OBMAT program. The initial assessment, consisting of ~~a physical examination and~~ an intake screening, shall be conducted by the medical director, an approved program physician or a supervised physician extender. The initial assessment shall focus on the individual's eligibility and need for treatment and shall provide indicators for initial dosage level, if required and if admission is determined appropriate. The determination of admission eligibility shall be made using accepted medical criteria such as those listed in the latest approved version of the Diagnostic and Statistical Manual for Mental Disorders.

20.3. The initial physical assessment shall include documentation of:

~~20.3.a. A brief physical examination;~~

§69-12-22. Controlled Substances Monitoring Program Database.

This section is too prescriptive and unnecessarily cumbersome. It is important to check the PDMP initially and thereafter at least every three months.

~~22.2. Program physicians shall access the database;~~ The physician or physician's designee shall access the PDMP for each patient in the program upon initial intake and then at a minimum of every three months thereafter.

~~22.2.a. At the patient's intake;~~

~~22.2.b. Before the administration of medication-assisted treatment medications or other treatment in an OBMAT program;~~

~~22.2.c. After the initial 30 days of treatment;~~

~~22.2.d. After any positive drug test; and~~

~~22.2.e. At each 90-day treatment review.~~

§69-12-24. Orientation.

The orientation section of the rule applies to OTPs and does not pertain to the patient/physician relationship in OBMAT programs. At most, an orientation to an OBMAT program could involve the physician or other staff member providing an explanation of the rules, rights, and responsibilities of the program, and then the patient signing an agreement. Further, this section includes references to dispensing medications, which is not done in OBMATs. We recommend that this section be deleted.

~~**§69-12-24. Orientation.**~~ [[Delete entire section.]]

§69-12-25 Required Services

We recommend this section be carefully aligned with nationally recognized treatment guidelines, such as ASAM's National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use.ⁱⁱ As written, there are several requirements that are out of step with nationally recognized treatment guidelines. For example, there is no clinical need for patients to have a physical and biopsychosocial assessment every 90 days. These should be conducted initially and then as clinically indicated. Requiring such frequent assessments serves no medical or therapeutic purpose and would surely increase costs to patients. Further, as explained in reference to Section 69-12-33, below, random drug testing is unwarranted and untenable in some cases.

~~25.2. Each OBMAT program shall require every patient to undergo a documented physical assessment by a program physician or a physician extender under the supervision of a program physician, before admission to the OBMAT program. The full medical examination shall be completed at the time of admission and prior to the first dose of medication-assisted treatment medication. The results of serology, toxicology and other tests must be completed within 14 days following admission.~~

25.4. Each patient accepted for treatment at an OBMAT program shall ~~be assessed including physical and~~ undergo a biopsychosocial assessments initially ~~and at least every 90 days following the initial assessment~~ by qualified personnel who shall determine the most appropriate combination of recovery-oriented services and treatment for the patient.

25.6. ~~Random drug testing of all patients shall be conducted during the course of treatment as required in section 33.~~ Each OBMAT program must provide adequate testing or analysis for drugs of abuse in accordance with generally accepted clinical practice.

~~25.10.a. Establish a strong working relationship with several treatment providers offering different levels of treatment;~~

§69-12-26 Counseling

There is no scientific evidence to support the frequency of required counseling sessions proposed in this rule, nor is there evidence to support a requirement for monthly individual counseling of patients who have had a positive drug screen.¹ ASAM's National Practice Guideline includes the following recommendation related to psychosocial treatment and treatment with buprenorphine:

Clinicians who are prescribing buprenorphine should consider providing or recommending office-based or community-based psychosocial treatment. There is some research evidence that the addition of psychosocial treatment improves adherence and retention in treatment with buprenorphine; however, these findings are mixed. It is recommended that clinicians offer patients psychosocial treatment early in their treatment with buprenorphine. Effective therapies may include the following:

- (1) cognitive behavioral therapies;
- (2) contingency management;
- (3) relapse prevention; and
- (4) motivational interviewing.²

Importantly, no one type or set frequency of psychosocial treatment is recommended for all patients. Instead, a patient's treatment plan – both the medication and the psychosocial treatment – should be individualized to the patient's unique needs. It is counterproductive, costly and contrary to accepted clinical practice to mandate a certain frequency or type of counseling service for all patients. As such, we recommend this section be revised to require physicians to provide, directly or by referral, office-based or community-based psychosocial treatments consistent with the recommendations of accepted national practice guidelines.

~~26.7. The clinical staff caseload ratio as defined in section 7.5.c. shall: [[Delete entire subsection.]]~~

~~26.8. Counseling sessions shall be provided according to generally accepted best practices and shall be offered: Counseling is an integral component of medication assisted treatment. Clinicians must ensure and document that patients receive adequate counseling services, individualized to each patient's needs. [[Delete remainder of subsection.]]~~

§69-12-27 Provision of Coordination of Patient Care; Post-Admission Assessment and Initial Plan of Care

The requirement that all patients undergo an "initial post-admission assessment" appears to duplicate the requirement in §69-12-20 that patients undergo a "pre-admission initial

assessment,” as well as the subsequent requirement in §69-12-28 that the program shall complete a physical and biopsychosocial evaluation of each patient within 30 days after admission. The three requirements are redundant (for example, each requires a physical examination (20.3.1, 27.2.c.1, and 28.3.a), a screen for communicable diseases (20.3.k, 27.2.c.7-10, and 28.3.h), and an inquiry to the Controlled Substances Monitoring Program (20.3.h, 27.2.c.11, and 28.3.f), among other things).

These redundant requirements for multiple and frequent assessments are not only not clinically necessary, but would be extremely costly for both the physician and the patient. We recommend these three sections be re-evaluated and streamlined to reflect national practice guideline recommendations for one initial assessment including appropriate medical history, physical examination, and laboratory tests to determine the appropriate course of treatment and individualized treatment plan. Only when clinically indicated should such a comprehensive patient assessment be repeated.

The final rule should also make explicit that all physical examinations and laboratory testing can be completed by a separate primary care provider for patients of those practices, such as psychiatric practices, that don’t have primary care services onsite.

~~27.2. Initial Post-Admission Assessments.~~ [[Delete entire subsection.]]

~~27.3.a.1. Follow-up physical examinations, by a program physician or a supervised physician extender;~~

§69-12-28. Comprehensive Physical and Biopsychosocial Evaluations.

This section is redundant; includes language about physical exams, which are not warranted in OBMAT program, as noted above; and the 30-day time frame conflicts with earlier sections of the rule. We recommend that the section should be deleted in its entirety.

~~**§69-12-28. Comprehensive Physical and Biopsychosocial Evaluations.**~~ [[Delete entire section]]

§69-12-29 Individualized Treatment Plan of Care

We recommend that patients who choose medically-supervised withdrawal be required to sign a consent form, to be included with their patient records, indicating they have been informed of the estimated risks of subsequent relapse, including the increased risk for death, as compared to treatment with opioid agonists.

29.1. Delivery of patient care and treatment interventions shall be based on the needs identified in the individualized treatment plan of care, which can be embedded in clinical notes.

29.8.a. OBMAT programs shall make every effort to retain patients in treatment as long as clinically appropriate and medically necessary in accordance with approved

national guidelines and acceptable to the patient and compliant with the treatment agreement.

~~29.8.b. At the time of the quarterly review, the patient shall again be presented with the option of participating in alternative treatment, such as medically supervised withdrawal. The patient shall sign and date a statement indicating whether he or she wishes to participate in an alternative form of treatment or remain within the program in an ongoing recovery-oriented maintenance format. The statement shall be included with the patient's individualized treatment plan of care.~~

~~29.8.c. If the patient chooses the option of participating in alternative treatment, the individualized treatment plan of care shall include a consent form signed by the patient acknowledging that under the detoxification protocol the strength of maintenance doses of medication-assisted treatment medication should decrease over time and that the participant is required to work toward a recovery-oriented lifestyle this should be documented in the clinical notes.~~

~~29.10. Coordination of Care Agreement. [[Delete entire subsection.]]~~

§69-12-30 Detoxification Program

This section includes references to methadone (30.9.e) and unsupervised take home medications (30.12.c) that are not relevant to office-based opioid addiction treatment. Such references should be removed for clarity's sake.

More importantly, the requirement in 30.14 to discontinue maintenance treatment after two continuous years should be struck in its entirety as there is no clinical evidence base to support discontinuation of treatment after two years. Even though the requirement includes an exception for continuation based on the clinical judgment of the medical director or program physician, it still perpetuates a misguided and unsubstantiated philosophy that treatment should be discontinued after some set amount of time.

Instead, ASAM's National Practice Guideline recommends the following regarding length of treatment with buprenorphine:

There is no recommended time limit for treatment with buprenorphine. Buprenorphine taper and discontinuation is a slow process and close monitoring is recommended. Buprenorphine tapering is generally accomplished over several months. Patients and clinicians should not take the decision to terminate treatment with buprenorphine lightly. Factors associated with successful termination of treatment with buprenorphine are not well described, but may include the following:

- (1) Employment, engagement in mutual help programs, or involvement in other meaningful activities.
- (2) Sustained abstinence from opioid and other drugs during treatment.
- (3) Positive changes in the psychosocial environment.
- (4) Evidence of additional psychosocial supports.

(5) Persistent engagement in treatment for ongoing monitoring past the point of medication discontinuation.

Patients who relapse after treatment has been terminated should be returned to treatment with buprenorphine.

Indeed, treatment length should be determined on an individual basis considering the clinical and social needs of each patient. No set timeframe should be mandated, recommended or suggested in this rule.

~~30.9.e. Provision for continuing care after the last dose of methadone or other medication-assisted treatment medication.~~

~~30.11. Short-Term Detoxification Treatment Services.~~ [[Delete entire subsection.]]

~~30.12. Long-Term Detoxification Treatment Services.~~ [[Delete entire subsection.]]

§69-12-32. Medical Withdrawal.

This section is more applicable to OTP programs and is not helpful for OBMAT programs. Besides, earlier sections of the rule covered short, long and administrative withdrawal. We recommend that this section be deleted.

~~§69-12-32. Medical Withdrawal.~~ [[Delete entire section.]]

§69-12-33 Laboratory Services; Drug Screens

There is no evidence to support the requirement that patients undergo monthly random drug testing. The ASAM National Practice Guideline notes that there is little research on the optimal frequency of testing, and that patients participating in office-based treatment with buprenorphine may be tested at each office visit. Requiring additional random drug testing outside a patient's routine monthly visit is both costly and not clinically indicated.

Additionally, requiring use of federally certified laboratories is not clinically necessary and is costly for patients. Qualitative tests using dipstick technology are generally sufficient for clinical purposes. The ASAM National Practice Guideline recommends testing should be done for buprenorphine, substances such as heroin and marijuana, and prescription medications including benzodiazepines, prescription opioids, and amphetamines. However, it does not call for quantitative testing and does not call for determining the type of benzodiazepine present (as 33.2.e.4 requires); qualitative testing for the presence or absence of these substances is sufficient to understand whether a course of treatment is working for a patient or inform adjustments to the patient's treatment plan.

Further, it is not necessary to require observation for every drug test, particularly for stable patients. There are generally other indicators that will alert a treatment provider to a problem with the patient apart from directly observing a urine drug test. Moreover, this requirement is not feasible for small practices, who may have to hire additional staff, and

can negatively impact a physician-patient relationship. We recommend this requirement be struck from the final rule.

Finally, the proposed requirements for weekly counseling and weekly treatment meetings following positive drug screens are not supported by any clinical guidelines or scientific evidence base. The proposed rule is also unclear as to the duration that these weekly sessions would be required. The requirement that patients be discharged from treatment or offered detoxification and then discharged following a fourth positive drug screen is punitive and not therapeutic. Such a requirement runs counter to the scientific understanding of addiction as a chronic disease that often involves cycles of relapse and remission. Episodes of relapse are not an indication that treatment should be terminated; instead, relapses should lead to a re-evaluation of the treatment plan and possible adjustment of medication dosage. We recommend this section (33.3) be struck in its entirety and be replaced with a simple requirement to document a re-evaluation of the patient's individualized treatment plan after each positive drug screen.

33.1. All patients in the OBMAT program shall undergo monthly drug testing during the first year of recovery. ~~Random drug testing of all patients shall be conducted during the course of treatment as required in section 33.~~

33.2.a. OBMAT programs shall ~~work carefully with toxicology laboratories to ensure valid, appropriate results of toxicological screens. Workplace testing standards are not appropriate for urine testing. Testing shall be done only by~~ send samples to laboratories with appropriate federal certification when necessary and clinically indicated.

33.2.d.1. ~~A patient receiving medication-assisted treatment medication maintenance services must at least one random drug screen per month during the first year of treatment and random drug screens quarterly thereafter.~~

33.2.d.3. ~~When using urine as a screening mechanism, all patient drug testing shall be observed to minimize the chance of adulterating or substituting another individual's urine.~~

33.2.e.1. Buprenorphine, ~~especially in~~ and frequently the ratio of ~~to~~ Norbuprenorphine/buprenorphine;

33.2.e.4. Benzodiazepines, ~~including testing procedures that detect diazepam, clonazepam, alprazolam and lorazepam;~~

33.3.b. A positive drug test result after the first six months in an OBMAT program shall result in ~~the following~~ a reevaluation of the patient's individualized treatment plan. [[Delete remainder of subsection.]]

33.3.c. Positive screens for tetrahydrocannabinol, delta-9-tetrahydrocannabinol, dronabinol or similar substances shall be carefully clinically evaluated ~~and shall in most cases result in reduction in take-home medication privileges unless other~~

~~action is considered appropriate by the medical director or program physician and primary counselor. Testing positive solely for tetrahydrocannabinol, delta-9-tetrahydrocannabinol, dronabinol or similar substances~~ any illicit drugs shall not serve as a basis for discharge from the program. Each OBMAT shall develop policies and practices based on sound clinical judgment and individualized for each particular patient.

33.3.e. Special precautions shall be taken when a patient has both sedatives and buprenorphine in their urine. This requires immediate discussion with the patient about the dangers and shall be noted in the patients' record.

§69-12-34 Special Populations

The burden for establishing agreements and coordination between medical practices and the criminal justice system should fall on the criminal justice system, which should be required to allow patients with opioid addiction to be treated with agonist or partial-agonist medications as clinically indicated. The court system and probation officers should be encouraged to work with the state's medical community to ensure justice-involved individuals with opioid addiction are able to access evidence-based care.

Further, while we fully support new legislation that requires pregnant women to receive priority for treatment opportunities, OBMAT providers cannot be expected to provide instruction on prenatal medical care, and patients should rely on their obstetricians for advice on prenatal care.

34.2.c. Each OBMAT program shall establish linkages with licensed behavioral health providers in the community or in the program's facility.

34.5.a. Pregnant women seeking and needing treatment shall be enrolled in the OBMAT program and provided treatment in accordance with guidelines and protocols from approved authorities. They shall be given priority in accordance with applicable state law.

34.5.b The OBMAT program shall ensure ~~that appropriate referrals for every pregnant patient who does not have an obstetrical provider, has the opportunity for prenatal care, either onsite or by referral.~~ Care for the pregnant patient with an opioid use disorder should be co-managed by the OBMAT program and the patient's obstetrical provider. ~~If the arrangement is by referral, the~~ The OBMAT program shall have agreements in place with the patient's obstetrical provider, including informed consent procedures, which ensure exchange of pertinent clinical information regarding compliance with the recommended plan of medical care.

~~34.5.c. If not available elsewhere, the program shall offer basic instruction on OBMAT maternal, physical and dietary care as part of its counseling services and document the provision of the services in the clinical record.~~

~~34.5.d. With respect to pharmacotherapy for opioid addicted pregnant women in medication-assisted therapy, the program shall ensure that: [[Delete entire subsection.]]~~

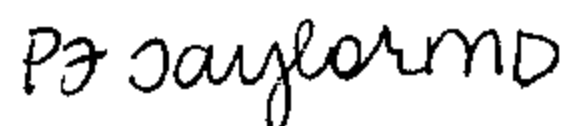
~~34.5.d.4. If a pregnant patient elects to withdraw from medication-assisted treatment, that withdrawal is not initiated by the program before 14 weeks and after 32 weeks gestation; perform regular fetal assessments as appropriate for fetal age and require that withdrawal is supervised by a physician experienced in substance use disorder medicine.~~

~~34.5.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 training. Any referral shall be documented in the patient's record.~~

~~34.6.a. Each OBMAT program shall establish agreements and develop and implement procedures to coordinate with agents of the criminal justice system on behalf of patients insofar as permitted by patient confidentiality requirements.~~

We would like to thank you again for the significant effort that has been put into this proposed rule and for the opportunity to provide comment. We look forward to continuing to work with the Department to ensure the final rule appropriately balances access to and quality of office-based opioid addiction treatment services in West Virginia.

Sincerely,



Paula Taylor, R.Ph., M.D.,
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The following organizations and individuals endorse this comment:

American Society of Addiction Medicine

WV Academy of Family Physicians

WV Perinatal Partnership

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 Edward W. Eskew DO, DABAM; Associate Medical Director, WVM PHP; Addictions Program Provider for Pretera Addiction Recovery Center
 Bradley Henry MD, RPh; President, Kanawha Medical Society; Vice President, WVSMA
 Hussein El-Khatib, MD; Distinguished Fellow, American Psychiatric Association; Former President of the APA, WV chapter; Chairperson, Ethics committee, APA, WV; Clinical associate professor, WVU; Private Practice; Medical Director, Med-Psych unit, Thomas Memorial Hospital; Board Certified & Recertified, General Psychiatry; Board certified & Recertified Addiction Psychiatry; Board Certified in Psychosomatic Medicine; Certified, American Association of Electro Convulsive therapy; Certified TransCranial Magnetic Stimulation (TMS); American Association of Electro Convulsive therapy
 Scott Gilchrist, MD; Co-owner & Psychiatrist, GR&W, Inc.
 Ryan Wakim, MD; President of GR&W, Inc.
 Curtis Arnold, DPM, WV Board of Medicine
 Mark Garofoli, PharmD, MBA, CGP
 Jeffrey Richmond, MD, board certified psychiatrist
 Robert E. Johnstone, MD; Professor of Anesthesiology, Interim Department Chair, West Virginia University
 Jeffrey V. Ashley MD, Chairman, WVU Department of Family Medicine, Charleston Division
 Andy R. Tanner, DO, Board Certified, American Academy of Family Physicians; Program Director, Osteopathic Family Medicine Program, CAMC

ⁱ Dugosh K, Abraham A, Seymore B, et al. A Systematic Review on the Use of Psychosocial Interventions in Conjunction with Medications for the Treatment of Opioid Addiction. *J Addict Med.* 2016;10: 93–103.

ⁱⁱ American Society of Addiction Medicine. National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use. June 1, 2015. Available at: <http://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf?sfvrsn=24>



August 5, 2016

M. Katherine Lawson, Inspector General
WV DHHR, Office of Inspector General
State Capitol Complex
Building 6, Room 817-B
Charleston, WV 25305

RE: 69 CSR 12 Medication-Assisted Treatment – Office-Based Medication-Assisted Treatment

Dear. Ms. Lawson:

The undersigned organizations, representing more than 1,200 West Virginia physicians and more than 3,900 physicians and allied health professionals across the nation who specialize in the treatment of addiction, write to provide comment on the Proposed Rule related to Medication-Assisted Treatment – Office-Based Medication-Assisted Treatment (OBMAT). We appreciate the extensive thought and effort that has already been put into the development of this proposed rule, and we are grateful for the opportunity to provide formal public comment.

We understand the purpose of the rule is to ensure that all West Virginia OBMAT programs conform to a common set of minimum standards and procedures to ensure the care, treatment, health, safety and welfare of their patients. We applaud this intent and share the Department of Health and Human Resource's concern for the quality of care offered to patients receiving OBMAT.

However, we are similarly concerned with ensuring continued access to evidence-based opioid addiction treatment in the office setting. The purpose of the Drug Addiction Treatment Act of 2000 (DATA 2000), which established the process for individual physicians to obtain a waiver to treat patients with addiction with FDA-approved Schedule III-V opioids in their office, was to improve treatment access and uptake by integrating addiction treatment into routine medical care. With the approval of the first buprenorphine product indicated for addiction treatment in 2002, patients could potentially access medication-assisted treatment from their personal doctor, rather than having to go to a separate opioid treatment program (OTP). Many physicians who offer this treatment do not run "programs" or "clinics," but instead treat patients with addiction as part of their normal medical practice. By proposing to regulate this treatment service as if it were being offered by specialty facilities like OTPs, the Department risks driving physicians away from

offering medication-assisted treatment, reversing the intent of DATA 2000, and eliminating access to treatment for many West Virginians for whom it is life-saving.

In fact, we have already learned that two physicians, one who practices in Nitro, and the other in Huntington, who treat a combined total of 130 patients, have both decided to discontinue their OBMAT practices due to the anticipated challenges of complying with onerous new rules. In addition, we have heard that more than 50 other physicians in the state who provide OBMAT to more than 2,400 patients also could stop treating their patients with addiction disorders due to these untenable rules. According to the CDC, West Virginia has the highest rate of drug overdose deaths in the country, and deterring providers from offering life-saving treatment can only exacerbate the problem.

Indeed, we anticipate that this proposed rule, if finalized as such, will unduly burden all physicians who offer this service and serve as a strong disincentive to providing such care. Further, we believe these regulations would have a disproportionately negative impact on small and solo physician practices. At a time when West Virginia is grappling with an epidemic of opioid addiction and overdose deaths, and at a time when federal authorities and the medical community are striving to expand access to OBMAT, we urge the Department to revise the rule as detailed below so that its laudable endeavor to ensure quality does not inadvertently restrict access to life-saving treatment.

The following comments are made with the intention of trying to balance the legislative goal of ensuring appropriate accountability to the Secretary, with a public health goal of ensuring access to quality care. For that reason, the undersigned groups believe that it is imperative to make the rules clear, simple, and useful, while not making them so cumbersome that otherwise willing and qualified physicians would be discouraged from providing treatment to a very vulnerable patient population.

For each section named below, we have included a description of and background information about the issue, followed by suggested changes to the specific provisions of the section.

DETAILED COMMENTS

The proposed regulations for OBMAT set forth registration, reporting, and other requirements that far exceed the current Federal requirements for Opioid Treatment Programs (OTPs). OTPs, under Federal rules, are not subject to patient limits (as OBMAT providers will be), and are authorized to dispense methadone, a Schedule II controlled substance. The Federal Government has recently finalized regulations for OBMAT providers who are interested in treating between 100 and 275 patients. The new rule, effective August 8, 2016, will require applications to the Federal Government, who can approve, deny, not renew, or revoke the approval at any time. In addition, these OBMAT providers must agree to connect patients to certain services, and are subject to annual reporting requirements. These new rules are intended to provide accountability, help reduce diversion, and help ensure that patients receive adequate care. West Virginia may

want to consider a similar, staggered approach, so that physicians who treat very few patients in rural and other settings are not dissuaded due to burdensome requirements.

For example, the rules could stipulate that they only apply to practices with more than 30 patients. Programs with 30-100 patients could be subject to lower fees and less stringent requirements, or be exempt from some requirements. All programs, regardless of size, are required to abide by federal regulations.

The WV OBMAT regulations could also include conditions under which physicians could obtain a waiver from the requirements, as the WV Legislature approved in SB 454, §16-5Y-6(d). We propose that physicians meeting one or more of the criteria below be eligible for a waiver from these requirements.

§69-12-XX. Waivers and variances.

XX.1. Physicians may obtain a waiver from the requirements set forth in this chapter if they treat 30 or fewer of the patients in their practice with OBMAT.

XX.2. Qualified physicians may obtain a waiver from the requirements set forth in this chapter, regardless of the number of patients in their practice treated with OBMAT, up to the maximum allowed by law, so long as they hold a current WV medical license, a valid DEA registration number, and meet one or more of the following conditions:

XX.2.a. The physician holds a board certification in addiction psychiatry or addiction medicine from the American Board of Medical Specialties.

XX.2.b. The physician holds an addiction certification or board certification from the American Society of Addiction Medicine or the American Board of Addiction Medicine.

XX.2.c. The physician holds a board certification in addiction medicine from the American Osteopathic Association.

XX.3. Physicians may apply for and obtain waivers or variances from the requirements in this rule, for reasons other than those enumerated above, by making written application to the secretary, explaining the rationale for the request, and describing how the physician will maintain quality of care for his or her OBMAT patients if the waiver or variance is granted.

§69-12-2. Definitions.

We appreciate the effort to create separate and distinct rules for Opioid Treatment Programs (OTPs) and Office-Based Medication Assisted Treatment (OBMAT) programs because of the significant differences between the two types of treatment for patients suffering from Opioid Use Disorder. Because of those significant differences, however, we feel it is imperative to include a definition for medication-assisted treatment. The definition

below is based on the definition used by the Substance Abuse and Mental Health Services Administration (SAMSHA).

We recommend the following specific additions and changes (additions are indicated by underscore and deletions by strike-through):

2. xx - Office Based Medication Assisted Treatment (OBMAT)—Treatment that combines the use of FDA-approved medications with evidence-based behavioral therapies for patients with opioid use disorders.

2.31. Mental Health Professional -- A person licensed under chapter 30 of the West Virginia Code as a social worker, psychologist or professional counselor, or as a physician who specializes in psychiatry.

2.33. Opioid Drug -- Any substance or drug having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug or substance having such addiction-forming or addiction-sustaining liability including, but not limited to, buprenorphine, fentanyl, heroin, hydrocodone, hydromorphone, methadone, morphine, codeine, Oxycontin, oxycodone, oxymorphone, and other medications that block the transmission of pain messages to the brain any natural, semi-synthetic or synthetic drug that acts primarily through any opioid receptor in the central nervous system.

§69-12-6 Registration of OBMAT programs: Fees and Costs

In this section, the requirement for separate registrations for each practice location seems unnecessary. Some physicians practice OBMAT at more than one location, primarily due to space limitations. An OBMAT program could operate with the same administration and professionals in more than one location, and it seems redundant to require separate registrations for each one. We understand the purpose of a requirement for separate registrations for facilities that operate independently or are not located in reasonably close proximity, so we recommend that the Secretary should have discretion to determine when separate registrations are warranted.

In regard to fees, unreasonably high and indeterminate fees could seriously impede clinicians' interest in providing OBMAT. Finding physicians who are willing to provide services to this group can be challenging enough without requiring large or unspecified fees. For programs with a small number of patients, the fee could be reduced or waived until they attain a certain number of patients. In determining the amount of the fees, the adjustment for consumer price index and reliance on number of registrants, as well as the unknown cost of the requisite inspection, seems unprecedented. Generally, licensure fees are set at a fixed amount, and the cost should include any necessary inspections. Further, charging twice as much for a renewal as compared to an initial registration seems counterintuitive.

Given the above concerns, we recommend the following changes:

6.1.b. A registration is valid only for the ~~location and persons~~ program named and described in the application.

6.1.c. Each OBMAT program location shall be ~~registered separately, identified on the application, regardless of whether the program is operated under the same business name or management as another program.~~ The Secretary shall have discretion to determine whether a separate registration is required for a particular location, such as if the locations operate with a significant degree of independence.

6.2.a. The owner(s) of an OBMAT program shall submit an application for ~~an~~ a new OBMAT program registration to the secretary not less than 30 days and not more than 60 days prior to the anticipated initiation of services.

6.3.a. All applicants for an initial, provisional or renewed registration shall be accompanied by a non-refundable fee in the amount required by this rule. ~~The annual renewal fee is based upon the average daily total census of the program. In addition to the set fee, the annual renewal fee shall be adjusted on the first day of June of each year to correspond with increases in the consumer price index.~~ The base amounts for initial, provisional and renewal fees are as follows:

6.3.a.1. Initial registration fee – \$250;

6.3.a.2. Provisional registration fee – only for existing programs as of the effective date of this rule seeking an initial license – \$250; and

6.3.a.3. Renewal registration fee – ~~\$500 plus adjustment~~ \$250.

~~6.3.b. An OBMAT program shall pay for the cost of the initial inspection made by the secretary prior to issuance of a registration. The cost of the initial inspection of an OBMAT program is \$250 plus the cost of the inspection and shall be billed to the applicant by the secretary.~~

§69-12-7 Administrative Organization and Management of OBMAT Programs

The proposed requirement that every physician practice offering medication-assisted treatment employ a separate program administrator would be prohibitively costly for most physicians. We believe these staffing requirements are far too onerous and should be eliminated in the final rule. Moreover, the proposed requirements related to the program administrator's education and experience are too prescriptive and would severely limit the applicant pool if this requirement for a separate program administrator is retained in the final rule. Many physicians employ only an office manager who may or may not have a bachelor's degree and likely would not have the amount of specialized experience detailed in the proposed rule. We believe this requirement would be too difficult for most physician practices to meet and would be an unnecessary barrier to care.

The proposed requirement that the medical director shall practice a certain number of hours per week could prevent many offices from functioning. There is no clinical or

therapeutic reason for this requirement, and the DEA already provides regulatory guidance on this issue. It also would preclude the use of telemedicine or telepsychiatry, since the physician would not be “on site.” Telemedicine and telepsychiatry have been the conduit for successful treatment of many patients in our very rural state.

The proposed requirement that each practice assign a primary counselor to each patient and ensure that there be at least one counselor for every 50 patients in the “program” is also excessive. There is no evidence to support such an arbitrary ratioⁱ and it has even been eliminated from federal regulations for OTPs. Additionally, it is unrealistic to require physicians’ practices to be able to document training and supervision of counselors who are used on a referral basis. Instead, we believe it is reasonable for a physician to document and demonstrate the qualifications of the counseling staff used on a referral basis as defined in Senate bill 454. That is, we believe it is reasonable for the Department to require that physicians demonstrate they are referring patients to counselors who are either licensed psychiatrists; certified alcohol or drug counselors; certified advanced alcohol or drug counselors; master’s level counselors, psychologists, marriage and family therapists, or social workers; or a bachelor level counselor working under the direct supervision of an advanced alcohol and drug counselor. Such documentation of the physician’s referral to a qualified counselor should be considered satisfactory.

7.1. Each OBMAT program shall identify a ~~program administrator~~, medical director, and, if applicable, a program administrator, program physician(s), and counseling staff.

7.2.a. The administrator of an OBMAT program ideally shall have ~~at a minimum~~ a bachelor’s degree in an appropriate area of study and a minimum of four years of experience in the fields of substance use disorders, behavioral health or health care administration or a master’s degree in an appropriate professional area of study and a minimum of two years of experience in the fields of substance use disorders, behavioral health or health care administration; or eight years of experience in the fields of substance use disorders, behavioral health or health care administration.

7.3.e. The medical director shall ~~practice 75 percent of the hours in which the OBMAT program is operating each week in order to ensure regulatory compliance and~~ carry out those duties specifically assigned to the medical director. Nothing in this rule prohibits an OBMAT from designating co-medical directors.

7.3.f. Within 10 days after the withdrawal or termination of the medical director, the owner or owners of the program shall notify the secretary of the identity of another medical director for the program. During the interim, not to exceed 60 days, another licensed physician shall be present during all hours of operation, or immediately available by telephone or telemedicine, except in the event of an emergency or unforeseen event, and shall assume the duties of the medical director on a temporary basis until such time as a new medical director is identified and begins work at the program. The interim physician may be another owner of the program or a program physician employed by or associated with the program.

7.5.c. Each OBMAT program's policies and procedures shall ~~establish ratios of primary counselors to persons served that are adequate to allow sessions to occur as mandated and that will allow persons served access to a primary counselor, either on site or by referral, but there shall be at least one counselor for every 50 patients in the program.~~ demonstrate that patients are actively engaged in addiction therapy through regular group and/or individual sessions with a therapist that occur at least weekly during the first three months of treatment.

§69-12-8 Environment and Operation of Office-Based Opioid Treatment Programs.

We understand the law requires that, prior to directly billing a patient for any medication-assisted treatment, a physician's practice receive either a rejection of prior authorization, rejection of a submitted claim, or a written denial from a patient's insurer or West Virginia Medicaid denying coverage. However, we also understand the law gives the Secretary the authority to grant a waiver or variance from this requirement. We strongly support the granting of such waivers to solo practitioners and small group practices that do not have the infrastructure required to submit insurance claims. Further, we encourage the Secretary to grant a waiver from this requirement to practices that treat patients who want to maintain confidentiality of their addiction treatment from their employer or insurer.

Sections 69-12-8.5 and -8.6, which would require "programs" to develop and implement policies and procedures for infection control and community relations, seem unnecessary for OBMAT programs and more appropriate for OTPs. Such requirements not only further the stigmatization of patients with addiction, but amount to burdensome administrative paperwork requirements that do nothing to promote the quality of care offered by a practice. In fact, by devoting time and resources to documenting efforts to avoid community disruption and developing "policies and procedures for soliciting patient and community ideas about medication-assisted treatment," physicians would be spending less time providing care, counseling patients and ensuring that their practices are meeting recommended clinical quality standards. A medical practice should be abiding by nationally recognized clinical practice guidelines, not community ideas of what treatment should be. It should be attentive to its patients' concerns and needs rather than those of non-patients who may hold stigmatizing views of persons with addiction. We recommend striking this section of the proposed rule to minimize unnecessary administrative requirements that do not contribute to treatment quality and avoid giving official credence to non-medical opinions about addiction treatment.

8.1.c.1. ~~The program shall notify the individuals receiving medication-assisted treatment services in writing at least 30 days in advance of their intent to close on Sunday or permanently change service hours.~~ All individuals patients shall receive an orientation addressing policies and procedures, and this orientation shall be documented in the individual's patient's record prior to receiving medications; and

8.2. Payments for services rendered may be made either by West Virginia Medicaid, Medicare, private insurance, or by cash ~~as described in 8.2.d.~~

~~8.2.a. The OBMAT program shall be eligible for, and not prohibited from, enrollment with West Virginia Medicaid and other private insurance.~~

~~8.2.b. Prior to directly billing a patient for any opioid treatment, the OBMAT program must receive either a rejection of prior authorization, or rejection of a submitted claim or a written denial from a patient's insurer or West Virginia Medicaid denying coverage for such treatment.~~

8.2.e.a. The OBMAT program shall document in the patient's record any rejection of prior authorization, rejection of a submitted claim for written denial from a patient's insurer or West Virginia Medicaid denying coverage for opioid treatment. The OBMAT program shall also clearly document in the patient's record if the patient has no insurance or has voluntarily and with full knowledge of the financial obligations, including all treatment costs, requested a claim not be submitted to their insurer or West Virginia Medicaid. When any instance described in this section regarding direct billing and acceptance of cash payments from a patient occurs, the OBMAT program shall clearly document in the patient's record the rationale and medical necessity for acceptance into the program.

~~8.2.d.b.~~ The OBMAT program may directly bill and accept cash payments from a patient ~~only after~~ if the requirements of sections 8.2.a., 8.2.b. and 8.2.e. herein, have been fulfilled and documented, or if the secretary has granted a waiver of this requirement.

~~8.5. Infection Control. [[Delete entire subsection.]]~~

~~8.6. Community Relations. [[Delete entire subsection.]]~~

§69-12-9. Facility Construction and Renovations; Life Safety Policies and Procedures

The provisions of this section seem more pertinent to OTPs, and we recommend that the section be deleted in its entirety. Subsections 9.1. and 9.2. refer to construction of OBMAT facilities, which might apply to an OTP seeking to expand its practice but does not seem relevant for existing OBMAT programs. Subsection 9.5 pertains to facilities which dispense medications, which are classified as OTPs, and it does not apply to OBMAT programs. It would be unprecedented for the DHHR to require a private physician practice to submit architectural drawings for approval prior to construction or expansion of their practice.

~~9.1. Before extensive construction or renovation of an OBMAT program facility begins, the program shall submit to the secretary for approval a complete set of the plans for the project, which includes the drawings and specifications for the architectural, structural and mechanical design and work.~~

~~9.2. The secretary shall advise the program whether approval has been granted. In the event the plans for the project are not approved, the secretary shall set forth in writing the reasons for the disapproval and provide the program the opportunity to~~

~~correct any deficiencies. Extensive construction or renovation of a facility may not begin until the secretary has issued final approval of the plans.~~

~~9.5. Life Safety Policies and Procedures. [[Delete entire subsection.]]~~

§69-12-13. Reports and Records.

This entire section is problematic. It was not required under SB 454, which stated that reporting requirements only applied to providers who dispensed medications to patients, and therefore does not include OBMAT providers. OBMAT providers would not be able to comply with the onerous requirements in this section. Private clinics do not have the ability to track this kind of data with any credibility; the requirements are consistent with grant-supported, research-level data collection and are not feasible in private practice.

~~**§69-12-13. Reports and Records.** [[Delete entire section.]]~~

§69-12-15. Risk Management.

There is no evidence or justification for the statement in 15.1.d.2.A., and it is contrary to current standard of care. It should be deleted. In fact, the entire subsection 15.1.d is overly prescriptive and interferes with physicians' ability to practice unencumbered under their medical licenses. 15.1.b. covers the provisions in 15.1.d., so we recommend that the entire subsection 15.1.d could be deleted.

~~15.1.d.2.A. The strength of maintenance doses of medication-assisted treatment medications should decrease over time, as clinically indicated; and~~

§69-12-16. Medication Security, Storage, Administration and Documentation.

This section seems to apply to OTPs and not to OBMATs; in fact, 16.5 states "An OBMAT program and its physicians shall not dispense or administer medication-assisted treatment drugs on site." Since OBMATs do not dispense or administer medications on site, then the entire section is unnecessary and should be deleted.

~~**§69-12-16. Medication Security, Storage, Administration and Documentation.** [[Delete entire section.]]~~

§69-12-17. Continuous Quality Improvement Policies, Diversion Control Plan.

Much of the language in this section applies to OTPs but is not applicable to OBMAT programs (e.g., "take home doses"). Further, "national outcome studies" are only required for OTPs, not OBMATs, and they would be prohibitively expensive for OBMAT providers. We recommend that the section be deleted, except for the following provisions.

17.1. Each OBMAT program shall develop, implement and maintain current quality assurance and quality control plans that include provisions for:

17.1.a. Regular and continuous staff education;

17.1.e.b. A service delivery assessment which, at a minimum, shall evaluate appropriateness of the individualized treatment plan and services delivered, completeness of documentation in patients; records and quality of and participation in staff training programs, linkage to a utilization of primary care and other out-of-program services, and availability of services and medications for other conditions;

17.1.g.c. An ongoing assessment, measurement and monitoring of patient outcomes, treatment outcomes and the various processes including, but not limited to:

17.1.g.c.1. Reduction or elimination of the patient's use of illicit opioids, illicit drugs and the problematic use of licit drugs;

17.1.g.c.2. Reduction or elimination of associated criminal activities;

17.1.g.c.3. Reduction of the patient's behaviors contributing to the spread of infectious diseases;

17.1.g.c.4. Improvement of quality of life through the restoration of physical and behavioral health and functional status, including employment or volunteerism, as may be appropriate; and

~~17.4.2. An OBMAT program shall maintain a current "Diversion Control Plan" (DCP) as part of its quality assurance programs that contains specific measures to reduce the possibility of diversion of controlled substances from legitimate treatment use. The DCP shall assign specific responsibility to the medical and administrative staff of the OBMAT program for carrying out the diversion control measures and functions described in the DCP. Each OBMAT shall have a plan to manage medication diversion as part of its policy and procedures.~~

§69-12-18. Patient Rights.

This section includes psychiatric jargon ["patients who act out"] and provides grievance procedures that are not required in all physicians' offices. Such procedures in OBMAT programs should be subject to the standard of care that applies to general practices. Further, it is a physician's prerogative to refuse to accept patients, and a requirement to provide a "full explanation" goes beyond the appropriate standards of care to which physicians are already bound

18.1.i. To be given a copy of the initial assessment, written acceptance into the program; or, in the case of denial of admission, ~~a full explanation as to the basis of the denial, and~~ a referral to another OBMAT program based upon the results of the initial assessment;

18.1.n. To be entitled to protection from other ~~patients who act out~~ patients' disruptive actions or behavior. The program shall attempt to determine the cause of that behavior so that an appropriate referral to an alternative method of care can be made.

~~18.2. The OBMAT program shall have patient grievance procedures which shall be displayed in the patient care area 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. The procedures shall inform the patients of the following: conform to the standard of care for physician practices.~~

~~18.2.a. The right of a patient to express verbally or in writing his or her dissatisfaction with or complaints about treatment received;~~

~~18.2.b. The right of a patient to initiate grievance procedures without fear of reprisal;~~

~~18.2.c. The right of a patient to be informed of the grievance procedure in a manner that can be understood by the patient; and~~

~~18.2.d. The right of a patient to receive a decision in writing with the reasoning articulated.~~

§69-12-19. Patient Records.

This section is more pertinent to OPTs than OBMATs. There are references to physical examinations, which are not done in OBMATs unless clinically indicated. To require every patient to undergo these routinely would increase costs and serve no medical or therapeutic function. Further, “individualized treatment plans” are written for OTPs, and inpatient and day hospital psychiatric patients. OBMAT practitioners write clinical notes regarding treatment plans. “Detoxification treatment plans” are contained in federal OTP language and are not appropriate for OBMAT programs.

~~19.7.e. All physical and biopsychosocial assessments completed every 90 days if clinically indicated;~~

~~19.7.f. Medical reports including results of the physical examination biopsychosocial assessment; family medical history; review of systems; laboratory reports, including results of required toxicology screens; results obtained from the Controlled Substances Monitoring Program database; and progress notes, including documentation of current dose and other dosage data;~~

~~19.7.i. The initial and post-admission individualized treatment plans of care, and any amendments, reviews or changes to the plans; The clinical notes;~~

~~19.7.j. Documentation that the services listed in the individualized treatment plan of care are available and have been provided or offered;~~

~~19.7.k. A written report of the treatment process; factors considered in decisions impacting patient treatment, e.g., take-home medication privileges, changes in counseling sessions, changes in frequency of toxicology screens; results from the~~

~~Controlled Substances Monitoring Program database; documentation of whether the patient was offered or accepted a detoxification treatment plan option; and any other significant change in treatment, both positive and negative;~~

~~19.7.q. Consent forms, releases of information, prescription documentation, travel and employment; and~~

§69-12-20 Pre-Admission Assessment; Admission Criteria and Admission Process

We recommend including the American Society of Addiction Medicine's (ASAM) criteria as acceptable and preferred criteria to use for assessing a patient and determining the appropriate level of care. ASAM's treatment criteria provide separate placement criteria for adolescents and adults to create comprehensive and individualized treatment plans. Adolescent and adult treatment plans are developed through a multidimensional patient assessment over five broad levels of treatment – including outpatient treatment – that are based on the degree of direct medical management provided, the structure, safety and security provided and the intensity of treatment services provided.

20.2. Any individual seeking admittance to the OBMAT program shall undergo a pre-admission initial assessment in order to determine whether the person meets the criteria for admission to an OBMAT program. The initial assessment, consisting of ~~a physical examination and~~ an intake screening, shall be conducted by the medical director, an approved program physician or a supervised physician extender. The initial assessment shall focus on the individual's eligibility and need for treatment and shall provide indicators for initial dosage level, if required and if admission is determined appropriate. The determination of admission eligibility shall be made using accepted medical criteria such as those listed in the latest approved version of the Diagnostic and Statistical Manual for Mental Disorders.

20.3. The initial physical assessment shall include documentation of:

~~20.3.a. A brief physical examination;~~

§69-12-22. Controlled Substances Monitoring Program Database.

This section is too prescriptive and unnecessarily cumbersome. It is important to check the PDMP initially and thereafter at least every three months.

22.2. ~~Program physicians shall access the database;~~ The physician or physician's designee shall access the PDMP for each patient in the program upon initial intake and then at a minimum of every three months thereafter.

~~22.2.a. At the patient's intake;~~

~~22.2.b. Before the administration of medication-assisted treatment medications or other treatment in an OBMAT program;~~

~~22.2.c. After the initial 30 days of treatment;~~

~~22.2.d. After any positive drug test; and~~

~~22.2.e. At each 90-day treatment review.~~

§69-12-24. Orientation.

The orientation section of the rule applies to OTPs and does not pertain to the patient/physician relationship in OBMAT programs. At most, an orientation to an OBMAT program could involve the physician or other staff member providing an explanation of the rules, rights, and responsibilities of the program, and then the patient signing an agreement. Further, this section includes references to dispensing medications, which is not done in OBMATs. We recommend that this section be deleted.

~~**§69-12-24. Orientation.**~~ [[Delete entire section.]]

§69-12-25 Required Services

We recommend this section be carefully aligned with nationally recognized treatment guidelines, such as ASAM's National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use.ⁱⁱ As written, there are several requirements that are out of step with nationally recognized treatment guidelines. For example, there is no clinical need for patients to have a physical and biopsychosocial assessment every 90 days. These should be conducted initially and then as clinically indicated. Requiring such frequent assessments serves no medical or therapeutic purpose and would surely increase costs to patients. Further, as explained in reference to Section 69-12-33, below, random drug testing is unwarranted and untenable in some cases.

~~25.2. Each OBMAT program shall require every patient to undergo a documented physical assessment by a program physician or a physician extender under the supervision of a program physician, before admission to the OBMAT program. The full medical examination shall be completed at the time of admission and prior to the first dose of medication-assisted treatment medication. The results of serology, toxicology and other tests must be completed within 14 days following admission.~~

25.4. Each patient accepted for treatment at an OBMAT program shall ~~be assessed including physical and~~ undergo a biopsychosocial assessments initially ~~and at least every 90 days following the initial assessment~~ by qualified personnel who shall determine the most appropriate combination of recovery-oriented services and treatment for the patient.

25.6. ~~Random drug testing of all patients shall be conducted during the course of treatment as required in section 33.~~ Each OBMAT program must provide adequate testing or analysis for drugs of abuse in accordance with generally accepted clinical practice.

~~25.10.a. Establish a strong working relationship with several treatment providers offering different levels of treatment;~~

§69-12-26 Counseling

There is no scientific evidence to support the frequency of required counseling sessions proposed in this rule, nor is there evidence to support a requirement for monthly individual counseling of patients who have had a positive drug screen.¹ ASAM's National Practice Guideline includes the following recommendation related to psychosocial treatment and treatment with buprenorphine:

Clinicians who are prescribing buprenorphine should consider providing or recommending office-based or community-based psychosocial treatment. There is some research evidence that the addition of psychosocial treatment improves adherence and retention in treatment with buprenorphine; however, these findings are mixed. It is recommended that clinicians offer patients psychosocial treatment early in their treatment with buprenorphine. Effective therapies may include the following:

- (1) cognitive behavioral therapies;
- (2) contingency management;
- (3) relapse prevention; and
- (4) motivational interviewing.²

Importantly, no one type or set frequency of psychosocial treatment is recommended for all patients. Instead, a patient's treatment plan – both the medication and the psychosocial treatment – should be individualized to the patient's unique needs. It is counterproductive, costly and contrary to accepted clinical practice to mandate a certain frequency or type of counseling service for all patients. As such, we recommend this section be revised to require physicians to provide, directly or by referral, office-based or community-based psychosocial treatments consistent with the recommendations of accepted national practice guidelines.

~~26.7. The clinical staff caseload ratio as defined in section 7.5.c. shall: [[Delete entire subsection.]]~~

~~26.8. Counseling sessions shall be provided according to generally accepted best practices and shall be offered: Counseling is an integral component of medication assisted treatment. Clinicians must ensure and document that patients receive adequate counseling services, individualized to each patient's needs. [[Delete remainder of subsection.]]~~

§69-12-27 Provision of Coordination of Patient Care; Post-Admission Assessment and Initial Plan of Care

The requirement that all patients undergo an "initial post-admission assessment" appears to duplicate the requirement in §69-12-20 that patients undergo a "pre-admission initial

assessment,” as well as the subsequent requirement in §69-12-28 that the program shall complete a physical and biopsychosocial evaluation of each patient within 30 days after admission. The three requirements are redundant (for example, each requires a physical examination (20.3.1, 27.2.c.1, and 28.3.a), a screen for communicable diseases (20.3.k, 27.2.c.7-10, and 28.3.h), and an inquiry to the Controlled Substances Monitoring Program (20.3.h, 27.2.c.11, and 28.3.f), among other things).

These redundant requirements for multiple and frequent assessments are not only not clinically necessary, but would be extremely costly for both the physician and the patient. We recommend these three sections be re-evaluated and streamlined to reflect national practice guideline recommendations for one initial assessment including appropriate medical history, physical examination, and laboratory tests to determine the appropriate course of treatment and individualized treatment plan. Only when clinically indicated should such a comprehensive patient assessment be repeated.

The final rule should also make explicit that all physical examinations and laboratory testing can be completed by a separate primary care provider for patients of those practices, such as psychiatric practices, that don’t have primary care services onsite.

~~27.2. Initial Post-Admission Assessments.~~ [[Delete entire subsection.]]

~~27.3.a.1. Follow-up physical examinations, by a program physician or a supervised physician extender;~~

§69-12-28. Comprehensive Physical and Biopsychosocial Evaluations.

This section is redundant; includes language about physical exams, which are not warranted in OBMAT program, as noted above; and the 30-day time frame conflicts with earlier sections of the rule. We recommend that the section should be deleted in its entirety.

~~**§69-12-28. Comprehensive Physical and Biopsychosocial Evaluations.**~~ [[Delete entire section]]

§69-12-29 Individualized Treatment Plan of Care

We recommend that patients who choose medically-supervised withdrawal be required to sign a consent form, to be included with their patient records, indicating they have been informed of the estimated risks of subsequent relapse, including the increased risk for death, as compared to treatment with opioid agonists.

29.1. Delivery of patient care and treatment interventions shall be based on the needs identified in the individualized treatment plan of care, which can be embedded in clinical notes.

29.8.a. OBMAT programs shall make every effort to retain patients in treatment as long as clinically appropriate and medically necessary in accordance with approved

national guidelines and acceptable to the patient and compliant with the treatment agreement.

~~29.8.b. At the time of the quarterly review, the patient shall again be presented with the option of participating in alternative treatment, such as medically-supervised withdrawal. The patient shall sign and date a statement indicating whether he or she wishes to participate in an alternative form of treatment or remain within the program in an ongoing recovery-oriented maintenance format. The statement shall be included with the patient's individualized treatment plan of care.~~

~~29.8.c. If the patient chooses the option of participating in alternative treatment, the individualized treatment plan of care shall include a consent form signed by the patient acknowledging that under the detoxification protocol the strength of maintenance doses of medication-assisted treatment medication should decrease over time and that the participant is required to work toward a recovery-oriented lifestyle this should be documented in the clinical notes.~~

~~29.10. Coordination of Care Agreement. [[Delete entire subsection.]]~~

§69-12-30 Detoxification Program

This section includes references to methadone (30.9.e) and unsupervised take home medications (30.12.c) that are not relevant to office-based opioid addiction treatment. Such references should be removed for clarity's sake.

More importantly, the requirement in 30.14 to discontinue maintenance treatment after two continuous years should be struck in its entirety as there is no clinical evidence base to support discontinuation of treatment after two years. Even though the requirement includes an exception for continuation based on the clinical judgment of the medical director or program physician, it still perpetuates a misguided and unsubstantiated philosophy that treatment should be discontinued after some set amount of time.

Instead, ASAM's National Practice Guideline recommends the following regarding length of treatment with buprenorphine:

There is no recommended time limit for treatment with buprenorphine. Buprenorphine taper and discontinuation is a slow process and close monitoring is recommended. Buprenorphine tapering is generally accomplished over several months. Patients and clinicians should not take the decision to terminate treatment with buprenorphine lightly. Factors associated with successful termination of treatment with buprenorphine are not well described, but may include the following:

- (1) Employment, engagement in mutual help programs, or involvement in other meaningful activities.
- (2) Sustained abstinence from opioid and other drugs during treatment.
- (3) Positive changes in the psychosocial environment.
- (4) Evidence of additional psychosocial supports.

(5) Persistent engagement in treatment for ongoing monitoring past the point of medication discontinuation.

Patients who relapse after treatment has been terminated should be returned to treatment with buprenorphine.

Indeed, treatment length should be determined on an individual basis considering the clinical and social needs of each patient. No set timeframe should be mandated, recommended or suggested in this rule.

~~30.9.e. Provision for continuing care after the last dose of methadone or other medication-assisted treatment medication.~~

~~30.11. Short-Term Detoxification Treatment Services.~~ [[Delete entire subsection.]]

~~30.12. Long-Term Detoxification Treatment Services.~~ [[Delete entire subsection.]]

§69-12-32. Medical Withdrawal.

This section is more applicable to OTP programs and is not helpful for OBMAT programs. Besides, earlier sections of the rule covered short, long and administrative withdrawal. We recommend that this section be deleted.

~~§69-12-32. Medical Withdrawal.~~ [[Delete entire section.]]

§69-12-33 Laboratory Services; Drug Screens

There is no evidence to support the requirement that patients undergo monthly random drug testing. The ASAM National Practice Guideline notes that there is little research on the optimal frequency of testing, and that patients participating in office-based treatment with buprenorphine may be tested at each office visit. Requiring additional random drug testing outside a patient's routine monthly visit is both costly and not clinically indicated.

Additionally, requiring use of federally certified laboratories is not clinically necessary and is costly for patients. Qualitative tests using dipstick technology are generally sufficient for clinical purposes. The ASAM National Practice Guideline recommends testing should be done for buprenorphine, substances such as heroin and marijuana, and prescription medications including benzodiazepines, prescription opioids, and amphetamines. However, it does not call for quantitative testing and does not call for determining the type of benzodiazepine present (as 33.2.e.4 requires); qualitative testing for the presence or absence of these substances is sufficient to understand whether a course of treatment is working for a patient or inform adjustments to the patient's treatment plan.

Further, it is not necessary to require observation for every drug test, particularly for stable patients. There are generally other indicators that will alert a treatment provider to a problem with the patient apart from directly observing a urine drug test. Moreover, this requirement is not feasible for small practices, who may have to hire additional staff, and

can negatively impact a physician-patient relationship. We recommend this requirement be struck from the final rule.

Finally, the proposed requirements for weekly counseling and weekly treatment meetings following positive drug screens are not supported by any clinical guidelines or scientific evidence base. The proposed rule is also unclear as to the duration that these weekly sessions would be required. The requirement that patients be discharged from treatment or offered detoxification and then discharged following a fourth positive drug screen is punitive and not therapeutic. Such a requirement runs counter to the scientific understanding of addiction as a chronic disease that often involves cycles of relapse and remission. Episodes of relapse are not an indication that treatment should be terminated; instead, relapses should lead to a re-evaluation of the treatment plan and possible adjustment of medication dosage. We recommend this section (33.3) be struck in its entirety and be replaced with a simple requirement to document a re-evaluation of the patient's individualized treatment plan after each positive drug screen.

33.1. All patients in the OBMAT program shall undergo monthly drug testing during the first year of recovery. ~~Random drug testing of all patients shall be conducted during the course of treatment as required in section 33.~~

33.2.a. OBMAT programs shall ~~work carefully with toxicology laboratories to ensure valid, appropriate results of toxicological screens. Workplace testing standards are not appropriate for urine testing. Testing shall be done only by~~ send samples to laboratories with appropriate federal certification when necessary and clinically indicated.

33.2.d.1. ~~A patient receiving medication-assisted treatment medication maintenance services must at least one random drug screen per month during the first year of treatment and random drug screens quarterly thereafter.~~

33.2.d.3. ~~When using urine as a screening mechanism, all patient drug testing shall be observed to minimize the chance of adulterating or substituting another individual's urine.~~

33.2.e.1. Buprenorphine, ~~especially in~~ and frequently the ratio of ~~to~~ Norbuprenorphine/buprenorphine;

33.2.e.4. Benzodiazepines, ~~including testing procedures that detect diazepam, clonazepam, alprazolam and lorazepam;~~

33.3.b. A positive drug test result after the first six months in an OBMAT program shall result in ~~the following~~ a reevaluation of the patient's individualized treatment plan. [[Delete remainder of subsection.]]

33.3.c. Positive screens for tetrahydrocannabinol, delta-9-tetrahydrocannabinol, dronabinol or similar substances shall be carefully clinically evaluated ~~and shall in most cases result in reduction in take-home medication privileges unless other~~

~~action is considered appropriate by the medical director or program physician and primary counselor. Testing positive solely for tetrahydrocannabinol, delta-9-tetrahydrocannabinol, dronabinol or similar substances~~ any illicit drugs shall not serve as a basis for discharge from the program. Each OBMAT shall develop policies and practices based on sound clinical judgment and individualized for each particular patient.

33.3.e. Special precautions shall be taken when a patient has both sedatives and buprenorphine in their urine. This requires immediate discussion with the patient about the dangers and shall be noted in the patients' record.

§69-12-34 Special Populations

The burden for establishing agreements and coordination between medical practices and the criminal justice system should fall on the criminal justice system, which should be required to allow patients with opioid addiction to be treated with agonist or partial-agonist medications as clinically indicated. The court system and probation officers should be encouraged to work with the state's medical community to ensure justice-involved individuals with opioid addiction are able to access evidence-based care.

Further, while we fully support new legislation that requires pregnant women to receive priority for treatment opportunities, OBMAT providers cannot be expected to provide instruction on prenatal medical care, and patients should rely on their obstetricians for advice on prenatal care.

34.2.c. Each OBMAT program shall establish linkages with licensed behavioral health providers in the community or in the program's facility.

34.5.a. Pregnant women seeking and needing treatment shall be enrolled in the OBMAT program and provided treatment in accordance with guidelines and protocols from approved authorities. They shall be given priority in accordance with applicable state law.

34.5.b The OBMAT program shall ensure ~~that appropriate referrals for every pregnant patient who does not have an obstetrical provider, has the opportunity for prenatal care, either onsite or by referral.~~ Care for the pregnant patient with an opioid use disorder should be co-managed by the OBMAT program and the patient's obstetrical provider. ~~If the arrangement is by referral, the~~ The OBMAT program shall have agreements in place with the patient's obstetrical provider, including informed consent procedures, which ensure exchange of pertinent clinical information regarding compliance with the recommended plan of medical care.

~~34.5.c. If not available elsewhere, the program shall offer basic instruction on OBMAT maternal, physical and dietary care as part of its counseling services and document the provision of the services in the clinical record.~~

~~34.5.d. With respect to pharmacotherapy for opioid addicted pregnant women in medication assisted therapy, the program shall ensure that: [[Delete entire subsection.]]~~

~~34.5.d.4. If a pregnant patient elects to withdraw from medication assisted treatment, that withdrawal is not initiated by the program before 14 weeks and after 32 weeks gestation; perform regular fetal assessments as appropriate for fetal age and require that withdrawal is supervised by a physician experienced in substance use disorder medicine.~~

~~34.5.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 training. Any referral shall be documented in the patient's record.~~

~~34.6.a. Each OBMAT program shall establish agreements and develop and implement procedures to coordinate with agents of the criminal justice system on behalf of patients insofar as permitted by patient confidentiality requirements.~~

We would like to thank you again for the significant effort that has been put into this proposed rule and for the opportunity to provide comment. We look forward to continuing to work with the Department to ensure the final rule appropriately balances access to and quality of office-based opioid addiction treatment services in West Virginia.

Sincerely,

PT Taylor MD

Paula Taylor, R.Ph., M.D.,
President, WVSMA

The following organizations and individuals endorse this comment:

American Society of Addiction Medicine

WV Academy of Family Physicians

WV Perinatal Partnership

R. Jeffrey Goldsmith, MD, DLFAPA, DFASAM, President, American Society of Addiction Medicine

Brad Hall, MD, DABAM, DFASAM, MROCC, AAMRO; Executive Medical Director, WV Medical Professionals Health Program; President, WV Society of Addiction Medicine; President, Federation of State Physician Health Programs

Ahmed Faheem, M.D., DABAM; President, WV Board of Medicine

Ralph S. Smith, Jr., MD, MBA, DABAM, DABPN in Addiction Psychiatry, Adjunct Clinical Professor, WVU School of Medicine, Department of Behavioral Medicine and Psychiatry
 Carl Rollynn Sullivan, MD, DABAM; Professor and Vice-Chairman, Director, Addictions Programs, WVU School of Medicine, Department of Behavioral Medicine & Psychiatry
 Adam Breinig, DO, President WV Academy of Family Physicians; Past President, WVSMA
 Amy N. Tolliver, MS, Director, WV Perinatal Partnership
 Edward W. Eskew DO, DABAM; Associate Medical Director, WVM PHP; Addictions Program Provider for Pretera Addiction Recovery Center
 Bradley Henry MD, RPh; President, Kanawha Medical Society; Vice President, WVSMA
 Hussein El-Khatib, MD; Distinguished Fellow, American Psychiatric Association; Former President of the APA, WV chapter; Chairperson, Ethics committee, APA, WV; Clinical associate professor, WVU; Private Practice; Medical Director, Med-Psych unit, Thomas Memorial Hospital; Board Certified & Recertified, General Psychiatry; Board certified & Recertified Addiction Psychiatry; Board Certified in Psychosomatic Medicine; Certified, American Association of Electro Convulsive therapy; Certified TransCranial Magnetic Stimulation (TMS); American Association of Electro Convulsive therapy
 Scott Gilchrist, MD; Co-owner & Psychiatrist, GR&W, Inc.
 Ryan Wakim, MD; President of GR&W, Inc.
 Curtis Arnold, DPM, WV Board of Medicine
 Mark Garofoli, PharmD, MBA, CGP
 Jeffrey Richmond, MD, board certified psychiatrist
 Robert E. Johnstone, MD; Professor of Anesthesiology, Interim Department Chair, West Virginia University
 Jeffrey V. Ashley MD, Chairman, WVU Department of Family Medicine, Charleston Division
 Andy R. Tanner, DO, Board Certified, American Academy of Family Physicians; Program Director, Osteopathic Family Medicine Program, CAMC

ⁱ Dugosh K, Abraham A, Seymore B, et al. A Systematic Review on the Use of Psychosocial Interventions in Conjunction with Medications for the Treatment of Opioid Addiction. *J Addict Med.* 2016;10: 93–103.

ⁱⁱ American Society of Addiction Medicine. National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use. June 1, 2015. Available at: <http://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf?sfvrsn=24>

Archived: Wednesday, August 10, 2016 12:34:34 PM
From: Lawson, Kathy M
Sent: Sunday, August 07, 2016 8:29:53 PM
To: Rutherford, Jennifer A
Subject: Fwd: Comments on OBOTPs Legislative Rule
Importance: Normal

Four of four

Kathy Lawson
Inspector General
Department of Health and
Human Resources

Begin forwarded message:

From: Mary Crouch <crouchcounseling@yahoo.com>
Date: August 7, 2016 at 7:46:42 PM EDT
To: KATHY.M.LAWSON@WV.GOV
Subject: Comments on OBOTPs Legislative Rule

Dear Kathy,

I wanted to comment on the proposed Legislative Rule 69-12 open for comment. I sent this to Secretary Bowling yesterday, but my former BBHMF colleague tells me it needs to come to you.

I have been working in and building programs using Office-Based Medication Assisted Treatment since 2005, specifically Suboxone. I have practiced in licensed behavioral health centers and in FQHCs as well as in Drug Court/Day Report Programs. I also spent 3 1/2 years working for Vickie Jones in BHMF and was the WV State Opioid Treatment Authority, so I am familiar with the Federal Legislation and WV's older Legislative rule that addressed only OTPs (Methodone programs).

Given that President Obama, Secretary Burwell and our West Virginia Secretary of DHHR, Secretary Bowling, all have the expressed goal of expanding access to Medication-Assisted Treatment to address the Opiate abuse and dependence epidemic, I think there are at least two provisions in 69-12 that are counter productive to that goal.

6.1.b A registration is valid only for the persons named and described in the application;

6.1.c Each OBMAT program location shall be registered separately, regardless of whether the program is operated under the same business name or management as another program.

These two provisions require our comprehensive behavioral health providers state-wide, private providers with multiple locations as well as our federally qualified health centers with multiple locations to draft, submit, monitor and pay for multiple registrations. This is an onerous burden that taxes both administrative personnel time as well as company finances and will thus dissuade providers rather than inspire them to operate multiple sites.

A second comment I would make surrounds the Program Administrator (section 7.2). The educational requirements listed are not particularly necessary as this is, in my experience, an administrative position. Clinical staff need the behavioral health / addiction background but ancillary staff need organizational and people skills.

Before I go, the description and requirements of the medical director read as if a program will likely require a specifically appointed medical director of the OBOT program as the medical director of the organization may not be the physician responsible for the MAT program. That being said, the designation "Medical Director" may well be redundant in many organizations.

Thank you and best regards,

Mary Aldred-Crouch

Mary Aldred-Crouch, MSW, MPH, LICSW, MAC, AADC,
Substance Abuse & Behavioral Health Services Provider

Archived: Wednesday, August 10, 2016 12:05:10 PM

From: Lawson, Kathy M

Sent: Sunday, August 07, 2016 8:30:33 PM

To: Rutherford, Jennifer A

Subject: Fwd: Rules of SB454 regarding Office-based medication-assisted treatment (OBMAT)

Importance: Normal

Should have been six total ... Five of six

Kathy Lawson
Inspector General
Department of Health and
Human Resources

Begin forwarded message:

From: "Lander, Laura" <llander@hsc.wvu.edu>

Date: August 6, 2016 at 11:57:01 PM EDT

To: "Kathy.M.Lawson@wv.gov" <Kathy.M.Lawson@wv.gov>

Subject: Rules of SB454 regarding Office-based medication-assisted treatment (OBMAT)

Dear Ms. Lawson,

I would like to offer my suggestions regarding the Rules of SB454 regarding office-based medication-assisted treatment. I am currently a therapist in the field of addictions and have been so for the last 22 years. I have worked in MAT with Buprenorphine for the last 10 years. Below I offer my insights and thoughts about the current proposed legislation with two concerns in mind. I believe the primary goals for West Virginia, which are also professional goals of mine, are to 1) increase access to MAT, 2) decrease abuse, diversion and irresponsible prescribing practices. These goals are at times can appear to be in conflict. As I see it, this legislation strives to strike a balance between the two which is not always easy, but necessary, to make MAT a successful intervention in our state.

I have reviewed the Title 69 series 12 rules and have the following comments in order of their appearance in the legislative document:

2 - Included in the definitions should be a definition of office-based medication-assisted treatment so as to distinguish it from OTPs.

6.1.b.c. & 6.3 - With the goal of increasing access to MAT, physicians who have multiple practices should not be penalized by having to register and pay separate fees for each site at which they prescribe.

6.3.b - Is this standard practice for any other clinic, that there is an additional fee for inspections? I would think that is what the OBMAT registration fees should cover.

7.3.e - This 75% rule does not make a lot of sense to me and I think it should be reduced.

7.5.c - This ratio regarding therapist to patient should be eliminated. In many settings including the one I work, we see patients weekly, bi-weekly and monthly. A therapist may have 4 monthly groups and 2 bi-weekly groups and 2 weekly groups which may be a total of 80 patients if each group had 10 people. This would exceed the current ratio requirement but in no way would inhibit the therapist from being able to treat all of his or her patients adequately due to the patients having different treatment needs and being seen in different frequencies. If a therapist is seeing 50 patients all in weekly individual therapy, that would certainly be too many, but with a phased

group model therapists can easily see more than 50 patients without compromising the quality of treatment.

8.1.c - This sounds like OTP language given that most OBMAT settings are not open on weekends.

8.2 - Medicare should be added to this list.

13.2 - This level of data collection and statistical reporting is too great and will be a huge burden for settings who do not have the man power to collect this data. It will discourage practitioners from wanting to be involved in OBMAT.

15.1.d.2.A - This is not always clinically indicated and buprenorphine maintenance does not support this practice nor does the research on maintenance tx. This statement should be removed.

16.1 - This is not relevant to OBMAT as they do not keep and dispense meds on site.

As indicated in 16.5

19.7.i and j. - Treatment plans are not standard practice in OBMAT as they are in OTPS. This language should be removed.

22.2 - This is too prescriptive regarding accessing the Board of Pharmacy website. The website should be checked at intake assessment and thereafter as clinically indicated.

24 - Is overly detailed and exhaustive. It would be of benefit to programs and to those who do site visits to have these orientation rules condensed.

25.2 - It would seem unnecessary that each patient would need to have a full medical examination. This is not needed prior to prescribing psychiatric medications and should not be required for OBMAT. Urine drug screen and a general blood panel as well as evaluation by physician should suffice.

26.7 - Again, the ratios should be eliminated for counselors because a counselor's case load can include multiple groups that have face to face contact monthly, bi-weekly or weekly allowing for higher ratios if a counselor sees only monthly patients.

26.8 - Counseling should occur at the frequency that is clinically indicated. Very few insurances will pay for twice weekly treatment without exhausting a person's benefits very quickly. Section 26 is highly prescriptive and takes away clinical judgment with can be a dangerous thing.

27 - I am not clear the function of the post-initial assessment. This sound like it may be OTP language. While this may be indicated in some cases it is not indicated in all situations and should be left to clinical discretion. The continued language in this section about treatment plans is not relevant to OBMAT but to OTPs.

28 - A full initial assessment has already been completed at the time of intake. There is no need for an additional comprehensive physical and biopsychosocial assessment at 30 days into treatment. Again there is not need for a full physical examination. All the things listed in this section here have already been assessed 30 days earlier in the initial assessment. This section can be removed.

29 - The treatment plan language is OTP language not relevant to OBMAT where progress notes are the primary means of ongoing assessment and planning. This section is not relevant to OBMAT.

29.8b - This is OTP language not appropriate for OBMAT.

33.1 - It does not make sense that all patients should have monthly drug testing as there may be some patients who only come monthly and others who come every other month. The language might be change to every other visit. 33.2.d.1 states the rule for drug screening frequency more accurately.

33.2.d.3 - Many settings do not have the staffing to observe every drug screen. It would be better to say settings must conduct observed drugs screens on a random basis or where clinically indicated.

34.5.d.4 - The American College of Obstetrics and Gynecology does NOT recommend that a pregnant woman withdrawal from medication during their pregnancy. It is against the policy of our program to facilitate this detoxification. If Detox is under some special circumstances indicated, it should be done on an inpatient basis.

Thank you so much for your consideration. I think we all have the same goals of increasing access to treatment responsibly. I appreciate all of your efforts towards this end.

Laura R. Lander, MSW, LICSW

Assistant Professor

Department of Behavioral medicine and Psychiatry, WVU

Archived: Wednesday, August 10, 2016 12:04:22 PM
From: Lawson, Kathy M
Sent: Sunday, August 07, 2016 8:30:44 PM
To: Rutherford, Jennifer A
Subject: Fwd: Comments on proposed rule: 69 CSR 12
Importance: Normal

Six of six

Kathy Lawson
Inspector General
Department of Health and
Human Resources

Begin forwarded message:

From: Frank Blackwell <frankblackwell@outlook.com>
Date: August 7, 2016 at 12:03:21 AM EDT
To: "Kathy.M.Lawson@wv.gov" <Kathy.M.Lawson@wv.gov>
Subject: Comments on proposed rule: 69 CSR 12

Dear Inspector General:

I have reviewed the office based guidelines proposed for Medication Assisted Treatment (MAT) programs. The proposed rules look like an attempt to make clinics that treat with buprenorphine follow the same rules as those that dispense methadone in daily doses. They are totally different. Using federal regulations written for Methadone clinics will be impossible for an office based physician operating a MAT program to comply with. Please review the proposed regulations to help providers offer their services that are so badly needed to help those in desperate need of addiction treatment. The last thing the State of West Virginia needs to lose with the Drug epidemic are addiction treatment services.

Thank You.
Delegate Frank Blackwell
West Virginia House of Delegates
3049225859 mobile

John Aldis, MD, PLLC

4911 River Road | (M) 304-283-0041 | (F) 304-870-4653 | (e-mail) jwaldis@gmail.com

August 8, 2016

M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capital Complex
Building 6, Room 817-B
Charleston, WV 25305

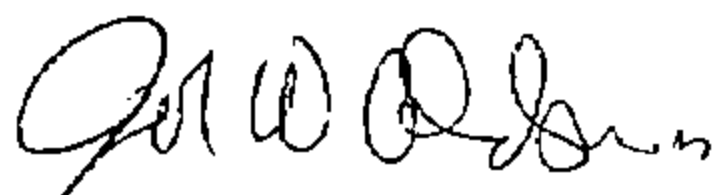
Dear Ms. Lawson:

I was offered the opportunity to comment on the proposed SB 454. I hope the comments and questions are useful. I have sent copies of this letter to several individuals (including the following) who may also want to participate in a discussion on my comments:

- Dr. Carl "Rolly" Sullivan (Director, Addictions Program, WVU)
- Ms. Kim Walsh (DHHR Charleston)

I have put my comments in the attached document. Please contact me if you have any questions. Thank you for offering to accept these comments.

Sincerely,



John Aldis, MD, PLLC
AAFP, MPH&TM

Enclosure:

Attached "Comments on SB 454"

Summary Comments:

If the intention of this new regulation is to assure that each patient who is fully compliant with the requirements imposed by the regulation and who is enrolled in a OBMAT program receiving care will receive a full range of useful services, it has done a good job of defining what that means.

If the intention is to increase access to adequate MAT in our region or state, or to make it easier for medical providers to provide this care, it will have the opposite result.

This law will discourage a great many physicians from even trying to treat patients with substance abuse. It makes it essentially impossible for any small clinic to provide this care. If this is the intention of the law, fine, but if not, there should be a section in the regulation describing how that is to be accomplished.

By restricting access to pill-mill dispensing of prescribed opiates (altogether a good thing), addicted patients were driven to the use of illicit opioids (e.g., heroin). This same "unintended consequence" is likely to occur when access to Suboxone/buprenorphine becomes more restricted.

More focused comments:

Most of the SB 454 document focuses on larger ("licensed") programs with little attention given for smaller clinics trying to assist in providing this care. There is no discussion in the document of requiring the larger clinics to provide support (psychiatric support, counselling support, etc.) to smaller clinics.

There is no mention in the law about the XDEA limit on the number of patients seen by a single provider as is proposed in the Comprehensive Addiction and Recovery Act (CARA). However, CARA suggests that providers with expanded BUP numbers (275/physician) must be either medical specialists in psychiatry or addiction medicine or work in a "licensed" MAT program (presumably a WV-described OBMAT program), this basically cuts off any possibility of the CARA accomplishing very much in WV.

Patients may (usually) need life-long MAT maintenance therapy. The law does not address how this is handled.

The proposed regulation gives very little attention to 12-step programs such as NA or AA or similar programs.

The definitions and roles in therapy of ancillary or adjunctive therapies are either not addressed or not clearly defined. While MAT must remain the cornerstone for therapy of addiction to opioids, some of

these other treatment modalities are very popular and sometimes useful. Who pays for them? How do they fit into the MAT programs?

The complicated interface between pain management and substance abuse treatment needs to be addressed.

Much of the proposed regulation appears to be written with WV Medicaid in mind with somewhat less consideration given to coverage by private insurance carriers.

Specific points:

I started a list of point-by-point questions. I finally gave up, but here are a few of them I jotted down before I quit.

Not specifically mentioning the role of the three forms of MAT might be addressed. These are three very different medications with different indications:

- Methadone (only provided in OTP clinics)
- Buprenorphine (including mono-product and combined with naloxone)
- Vivitrol (not a narcotic; not a controlled drug; no DATA-2000 limit on the number of patients who can receive the medication)

(n.b., Does this regulation cover Vivitrol under the same requirements as for buprenorphine?)

(n.b., A number of clinics now use buprenorphine or methadone and even Vivitrol to treat patients. Would such a clinic under this regulation be treated as an OTP or an OBMAT?)

Since OHFLAC is given the responsibility of oversight of all OBMAT program, it would be important to define OBMAT somewhere.

- For instance, does this regulation apply to all clinics treating patients with MAT, regardless of payment procedures?
 - Does it include clinics only prescribing Vivitrol (a non-narcotic, but still MAT)?
 - Is a solo-provider's office treating patients with BUP an OBMAT? Is he not allowed (in the context of this regulation) to treat addiction with BUP unless s/he declares his practice to be an OBMAT? (Is this requirement in conflict with DEA/FDA regulations and state medical licensure?)
- (n.b., OBMAT is not found anywhere on the SAMHSA web site. A Google (OBMAT opioid) found only 22 hits, most of which were not relevant and of those that were, many were expressing concerns that the new DHHR rules will seriously compromise the ability of small/solo/rural MAT-providers to continue to provide services.)

2.3. Advanced Practice Registered Nurse --

Why do you include the definition for Advanced-Practice Nurses but not for Physician Assistants?

2.5. Approved Authorities

This regulation does not mention SAMHSA. That group is probably the most important for our programs. While probably not a group used to provide "approval" for state-run programs, it remains (or should be) a center for how to focus treatment programs.

2.18. For-Cause Inspection

(n.b., Perhaps this should also include inspection to assure coding and billing procedures are in line with appropriate guidelines and the insurance companies' policies.)

2.29. Medication Administration –

(n.b., The use of “direct-observed therapy) for buprenorphine as a mono-product or as Suboxone is becoming more common in treatment facilities. Perhaps this definition can include that as one form of “medication administration.”)

2.31. Mental Health Professional -- A person licensed under chapter 30 of the West Virginia Code as a social worker, psychologist or professional counselor.

(n.b., Of course, you meant to include psychiatrists.)

2.34. Opioid Treatment Services -- Treatment and services provided by an OBMAT program that uses medication-assisted treatment medications as a part of its treatment modality. Opioid treatment services may be provided through intensive outpatient, residential or hospital settings; and may include medical maintenance, medically supervised withdrawal and detoxification, various levels of medical, psychosocial and other types of care, detoxification treatment, and maintenance treatment.

(n.b., This definition excludes all the “holistic” “adjunctive” therapies unless they are done in concert with MAT. Was that intentional?)

2.37. Physical Dependence -- A state of biologic adaption that is evidenced by a class-specific withdrawal syndrome when the substance is abruptly discontinued or the dose rapidly reduced, or by the administration of an antagonist.

(n.b., Suggest following this definition with Physical Addiction?)

2.41. Positive Drug Screen –

Suggest defining “drug screen” first, describing the purpose/intention of the testing and perhaps comment on the “screening” or “point-of-care” level of testing and “LCMS” or “confirmatory” levels of testing and perhaps mention that the tests may include urine, saliva, blood, and/or hair.

8.1.c.2. The program shall establish procedures for emergency access to dosing information 24 hours a day, seven days a week. This information may be provide [sic] via an answering service or other electronic measure. Information needed includes the patient's last dosing time and date, and dose.

(n.b., It is not entirely clear what this section is saying.)

16.7. Prescriptions

The description of what needs to be on each prescription is a bit unusual:

- (patient's?) full name
- physical address
- diagnosis code for which the medication is being prescribed
- drug name, strength, dosage form, quantity and directions for use
- the OBMAT program's license or registration number
- the prescribing program physician's regular DEA number and DATA 2000 identification number, if applicable

The Board of Pharmacy also wants the physician's

- full name
- NPI,
- WV license number,
- Address,
- phone number,
- fax number.

§69-12-6 Registration for OBMAT programs; Fees and Costs.

(n.b., Would any physician in private or solo practice put himself through this?)

§69-12-7. Administrative Organization and Management of OBMAT Programs.

(n.b., Again, impossible for a small or solo practice.)

7.4.a. The OBMAT program may employ and use program physicians, physician extenders and other health care professionals working within their scope of practice who have received sufficient education, training, experience, or any combination thereof, to enable that person to perform the assigned functions. All physicians, nurses and other licensed professional care providers must comply with the credentialing requirements of their respective professions. The OBMAT program may only employ registered nurses, advance practice registered nurses and physician's assistants as physician extenders.

(n.b., this conflicts with the definition of physician extenders.)

7.5.a. Counseling through an OBMAT program shall be provided by counseling staff that meet the qualifications as described W.Va. Code § 16-5Y-5(d).

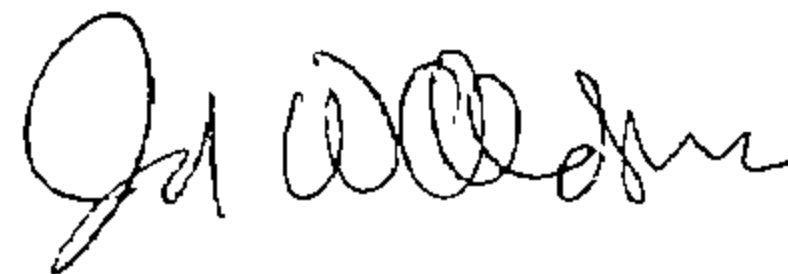
(n.b. This is important. Where can that code be found?)

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

(n.b., What does this mean? Multiple admissions to this OBMAT, or other OBMATs or other treatment facilities?)

Sorry, I quit reading at that point. I hope you find any of this useful.

Respectfully,



John W. Aldis, MD, PLLC
AAFP, MPH & Tropical Medicine

**DATE WRITTEN COMMENT PERIOD ENDS
Sunday, August 07, 2016 4:00 PM**

**WRITTEN COMMENTS MAY BE MAILED TO
M. Katherine Lawson, Inspector General
WV DHHR, Office of Inspector General
State Capitol Complex
Building 6, Room 817-B
Charleston, WV 25305**

To: Katherine Lawson

From: Susan King (304-532-1686)

Date: August 4, 2016

RE: Comments: Payment of Services for Opioid and MATP programs

My concern is payment for the services by the individuals who are needing the treatment.

Usually, by the time the Consumer/Patient/Client seeks treatment they are "per-se" at the bottom of the financial ladder (i.e. divorces, no contact with family, living on the streets, homeless, no job, no place to live, no one to help them, owe 'back pay' in child support, jail and court fines, school loans or even overdose/medical bills on top of all the other expenses and their mental issues). The C/P/C could even be a "fine-upstanding citizen" but due to medical problems that may have helped to cause the addiction.

The burden to pay for the services even though they may be willing to pay for them could be too overwhelming for the Consumer/Patient/Client and could cause the C/P/C to relapse.

I would like to recommend some type of support system (financial or grants) for when the C/P/C starts the system/program and when they are finished.

Yes, I understand Medicaid will pay for some of the services and supposedly, commercial or TPA insurances, but those people who do not have insurance and, presumably, some of them will not qualify for Medicaid services could cause undue financial stress on the C/P/C causing them to possibly relapse.

Please recommend to the state of West Virginia to 'come up' with some type of funding to get the C/P/C the financial help they may need to complete the MATP program and enable them to become productive members of our society (again) including working with WV Workforce and WV Dept. of Rehabilitation or any other program that the government may be able to offer.

Suggestions for funding: work programs, volunteering in society, cleaning up parks/river streams, helping with the flood victims, hospital volunteering, picking up trash, emptying trash cans, sweeping sidewalks, cleaning cemetery grave markers or other types of programs.

Just a hopeful, helpful thought for the victims who may be a product of their environment or demise.

If you would need to reach me via email, my email address is listed below:

Smking2007@hotmail.com

Comments for Title 69, CSR 12, Series 12 of Medication-Assisted Treatment – Office –Based Medication-Assisted Treatment

69-12-2.10 – Definition of Counselor- It never states the educational requirements for this position. This could be read as either a Bachelor's level or Master's level provider. I would propose that if Bachelor's level providers are included, they be certified by the nationally recognized credential either (1) Alcohol and Drug Counselor, or (2) Advanced Alcohol and Drug Counselor. (will be described later in a future comment).

69-12-2.20 -Individualized Treatment Plan of Care/Treatment Plan- planning and goals should already be addressed in progress notes, which physicians and counselors are required to document for each encounter, per insurance requirements. Having treatment plans, in addition, would just create extra paperwork when the content is already included elsewhere in the patient's chart. (Suggestion: delete this requirement)

69-12-2.31 – definition of mental health professional – again, this does not clarify the level of education providers should have.

69-12-2.33 – Opioid Drug – including oxycontin and oxcodone is redundant. (Suggestion: strike Oxycontin, the brand name)

69-12-6.1 – Requiring separate registrations – While this sounds reasonable, some physicians and teams may be providing services at multiple locations. For example, Chestnut Ridge/Behavioral Medicine has a separate physical address from WVU-Hospital, even though we are 50 feet apart. We then have another off-site location across town, but still have the same providers. It seems more logical to require separate registrations when the (1) primary treatment team differs between sites, (2) program director, medical director, or providing physicians differ, (3) program rules/patient requirements differ, (4) or some other type of variance. Additionally, how will TelePsych programs be accounted for, or will they be counted as wherever the provider's physical location is?

69-12-6.3.a. – Registration application – calculated based average daily census. I am unsure how feasible it will be to actually calculate these numbers. Additionally, I'm not sure what the purpose is of the census. If the idea is to get a sense of how many patients are being treated, the number would be inaccurate; patients early in program attend multiple times per week; patients further in the program would attend fewer days. Moreover, if patients opt to attend additional services (extra therapy, psychiatry), this would further skew the numbers. Having the number of encounters per patient might be more useful, and also further stratifying by amount of clean time. Additionally, if an office is only open part of a day, that

would also skew overall numbers. However, this data is still going to be tricky to obtain and has a high potential of being inaccurately calculated.

69-12-6.3.a.3 – Renewal fee – For what is the \$500 fee adjusting? If the cost of applications/licenses is going to vary, it would be most logical to make it based on number of patients. It does not seem logical to charge very small practices the same fee that large practices pay. It has the potential to be a large deterrent for rural practices or practices with only a few patients in need of this type of service.

Example of proposed Renewal Fee schedule	
# of patients	Cost
1-5	\$50
6-20	\$75
21-50	\$100
51-100	\$125
101-200	\$200
201+	\$300

69-12-6.5.a.5 – medical director must be practicing – How is “practicing” being defined. It would be helpful if something mentioned availability of face-to-face encounters, so that Telepsych programs would be included. This would hopefully also exclude the director from just calling in and checking on things from afar.

69-12-7.c.1 – time frame for completion- there is not a specified time frame in which the plan to become competent should begin. This would allow the medical director to provide services and not start this program until close to the end of the 12-month period.
(Suggestion: To begin within first 2 weeks or month of appointment/hiring)

69-12-7.3.d.5. – approving continuing education – Nowhere is it specified as to the type of continuing education providers should be receiving. (Suggestion: require so many hours for each profession. For example, Social workers are required to have 40 hours of CEU’s every 2 years. Maybe 20 of those should have to be related to treatment. Since nurses and physicians also have CEU’s, ideally these would be tied in so that (1) the format of continuing education is known, (2) the continuing education has previously been approved by the professional board for each provider. Alternatively, the nationally recognized Alcohol and Drug Counselor and Advanced Alcohol and Drug Counselor certification and recertification requires 40 hours of addiction-related CEU’s every 2 years². Making counselor’s obtain or work toward obtaining ADC or AADC certification would ensure the appropriate type of ongoing education occurs.

69-12-7.3.e Medical Director practicing – How will the 75% be calculated? This doesn't clarify if they have to be in person, available for telepsych, etc.

69-12-7.4.a – professional medical staff – How is “sufficient education, training, experience, or any combination of the above” be determined? Ideally, providers would have a base knowledge of addiction education and it be ongoing. (Suggestions: professional medical staff must have a minimum of 20 CEU/CME hours that are addiction-specific, attended an addiction specific training program (such as a fellowship or addiction-counseling), or have previously worked in a recovery-oriented treatment program). Moreover, the way 7.5.f currently reads, other non-physician staff have a minimum topics listed they must be informed on, so including something like this for physicians makes sense. This list for physicians should definitely should include pain, per 34.4.

69-12-7.4.b.2.A – enrollment in plan of education – There is no way for standardization the way it is currently written. Requiring that the education plan be approved by an addiction-based, nationally-recognized program/agency or approved CME's would allow for a more standardized plan with accountability.

69-12-7.5.c – Staff to patient ratio – 1:50 is an arbitrary number. The way it currently reads, if a therapist has 3 groups of 12 different patients she sees monthly, she can only see 14 more patients the entire rest of the month. (Suggestion: No ratio should be established, as it will vary based on client attendance and continued program involvement. As long as the treatment requirements are being met, such as clients getting the necessary therapy, the ratio should not exist.)

69-12-7.5.f. – training for new employees – training on addiction-related issues should have some type of standardization, as mentioned in previous comments. State Board-approved CEU's or ADC/AADC license would seem reasonable.

69-12-7.5.g – exemption for experienced counselors – this is worded strangely. (Suggestion: An experienced counselor from another MAT program that is newly employed with an agency may be exempt from the mandatory initial training if they can provide documentation proving they have had a minimum of 20 hours of recent (within the past 2-3 years) addiction-specific training OR have more than 5 years of experience in addiction/recovery.)

69-12-8.2.b – direct billing – this does not include the client's voluntary choice to pay out-of-pocket, prior to billing insurance. Only denials of insurance is discussed.

69-12-8.2.c – documentation of payment, self pay – This still would allow providers to claim they accept insurance, but have every patient just sign a waiver form that says they prefer to private-pay rather than go through the insurance. (Suggestions: (1) providers must report what % of clients are private pay, (2) A minimum of 30% [randomly chosen] of clients must

be billed through insurance and/or state Medicaid, unless they have fewer than 5 [again, randomly chosen] patients).

69-12-9.6.a – access to staff – There is no need to have 24/7 staff availability. Patients are provided take-home medication and would, presumably, receive this during normal business hours.

69-12-11.1.c. – plans of correction – Who is the governing body? Might be helpful to clarify is this the medical director or administrator, or someone else.

69-12-13 – reports and records – Would like to have providers report source of payment: insurance and cash/private pay.

69-12-14.1 – credentialing – as previously mentioned, so many hours should be addiction/treatment-specific. This would also be another opportunity to clarify what level of education the counselors should have.

69-12-16.4.a – dosage – dosing procedures are not relevant, since OBMAT provide prescriptions and not medication. This is clarified in 16.5, which makes this piece irrelevant. (Suggestion: Strike this section)

69-12-17.4 – Diversion Control Plan – there is no mention of this being updated periodically. Might be reasonable to have it revisited every 2 years.

69-12-19.7.c - initial assessment report- by whom is this provided? The doctor? The counselor? A case worker? If this is by the counselor, it could be combined with 19.7.d.

69-12-19.7.e - redoing psychosocials – redoing this every 3 months is cumbersome and unnecessary. Major changes would be updated in routine progress notes. Insurance suggestions are that this be redone every year. If redoing psychosocials isn't removed from the law/rules, I would suggest it defer to the insurance standard.

69-12-19.7.k – report of treatment process – take home medications is not relevant. Quantity of medication or duration of script (1 day, 3 days, 1 week, 1 month, etc) may be more appropriate language. (Suggestion: remove take home medication privileges)

69-12-19.8.b. – completing an entry – This contradicts 26.12, where it states documentation needs to be done within 72 hours. Centers for Medicare and Medicaid Services have not defined a time for entry completion, but instead have this, “The service should be documented during, or as soon as practicable after it is provided in order to maintain an accurate medical record.” In **Medicare Claims Processing Manual says in Publication 100-04, Chapter 12, Section 30.6.1 A¹. (Suggestion: Rephrase that documentation be completed “as soon as practicable after it is provided in order to maintain an accurate medical record” to be concordant with the federal standard.)**

69-12-25.5 - post-admission assessment - there would not be expected to be significant changes within the first 7 days. If there are, this would be documented in ongoing progress notes. Requiring another assessment in such a short time-frame is redundant and not a good use of time.

69-12-25.7. – counselor – level of education of counselor not specified, as previously mentioned in other comments.

69-12-26.4 – counseling matters - would be nice to include co-occurring/dual diagnosis as 26.4.c

69-12-26.67.a – diversity – may not be possible and priority should be on having well-trained professionals (Suggestion: shall try to have an appropriate clinical mix of...)

69-12-26.12 – is more logical to follow with state insurance requirements, as suggested above.

69-12-27.2 – is this different from the psychosocial assessments or treatment plans or physician assessment? The way it currently is written now there would be two within 7 days.

69-12-28.1 another assessment/evaluation within 30 days. This information will primarily be the same as the initial psychosocial assessment. Redoing this again in 30 days is unnecessary and not a valuable use of time. If we reference 25.5 and 28.1, this would actually be the 3rd assessment in 30 days of the same type. It makes more sense to follow with insurance that this is redone annually.

69-12-29 – Treatment plans – should eliminate treatment plans. This is documented in an ongoing, up-to-date manner within the progress notes. Rules, expectations, and policies are already outlined upon admission.

69-12-29.8.b - It seems that the words detox and withdrawal are being used interchangeably, but they are not the same.

69-12-29.8.e - It seems that the words detox and withdrawal are being used interchangeably, but they are not the same.

69-12-30 - It seems that the words detox and withdrawal are being used interchangeably, but they are not the same.

69-12-30.9.e. – eliminate word “methadone”

69-12-30.11.b – “unsupervised doses” and “take home” medication are irrelevant. Medication is not going to be administered on site daily, and the only administration that should occur at all is for providers who choose to do formal induction on site. (Suggestion: Eliminate 30.11b-30.12.c)

69-12-30.14 –discontinuing maintenance treatment – the standard of 2 years is arbitrary. This has not been supported by research.

69-12-31.4.b – include violating peer confidentiality

69-12-31.6 – female patients – this assumes compliance. (Suggestion: It should say something along the lines of “if female patients who have a positive pregnancy test are noncompliant with treatment and/ or continue to relapse/engage in poly-substance use then they may be discharged if the primary treatment team determine they can no longer provide safe provision of medication, when considering risks and consequences.)

69-12-33.c – positive UDS for THC – discharge from the program due to ongoing use should be up to the treatment team’s discretion.

69-12-34.1.b – cocaine should not be specifically listed. More appropriately, it should read “alcohol, illicit drug use, and other drug abuse”. However, this is redundant, because previously it reads that staff must be appropriately trained.

69-12-34.2.b - It seems that the words detox and withdrawal are being used interchangeably, but they are not the same.

69-12-34.4.a - It seems that the words detox and withdrawal are being used interchangeably, but they are not the same.

69-12-33.b. –additional therapy for positive UDS – there is no time frame specified. How long must clients be receiving this minimum of counseling? 1 month? Until a negative UDS occurs? Until treatment team say okay?

69-12-34.5.d.4 – pregnant patient – This still assumes compliance. See above comments for 69-12-31.6.

1. **Medicare Claims Processing Manual Chapter 12 - Physicians/Nonphysician Practitioners** <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c12.pdf>
2. **West Virginia Certification Board**
For Addiction & Prevention Professionals <http://www.wvcbapp.org/>



RECEIVED

AUG 08 2016

Inspector General

Jeffrey M. Richmond, M.D.
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RE: Proposed Rule 69-12 regarding OBMAT for opioid dependence.

Dear Inspector General, M. Katherine Lawson,

I am a board certified psychiatrist providing MAT to patients with opioid addiction in Wheeling, WV and Morgantown, WV. I write to voice my concerns regarding rule 69-12 in its current form. I must first say that I applaud the effort on the part of the state to eliminate the handful of very poor quality MAT clinics which exploit patients with addiction for financial gain with little regard to quality of treatment and impact on community. These programs give MAT a bad name and threaten to turn public opinion against this incredibly valuable weapon in the fight against opioid related overdose deaths. With that said, I believe that this could be accomplished with a few simple rules. Should this rule take effect in its current form, I fear that many providers will be unable to continue providing this life saving treatment. This comes at a time when limited access to treatment is already contributing to the deaths of West Virginians on a regular basis. I know that my own provision of MAT would cease, should this regulation take effect in its present form.

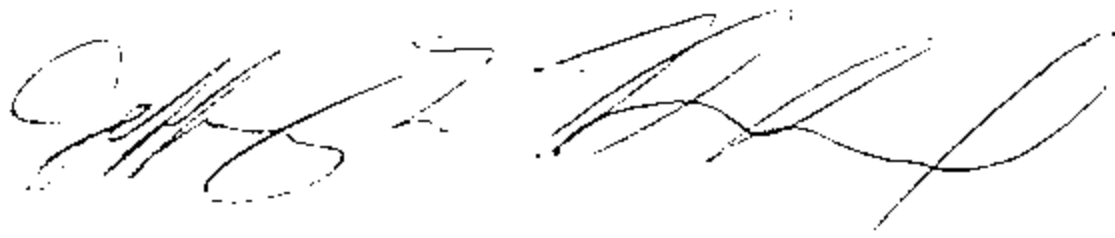
I believe that simply requiring providers to accept and bill insurance for buprenorphine-related care and offer counseling, either on site or by referral, would be sufficient to discourage most bad actors from participating in MAT. While it may be ideal to provide comprehensive services to patients with opioid addiction in a centralized location, the geography of this state and availability of resources makes this impossible. Considering that many of the patients with the most dire need of treatment depend on Medicaid (a program notorious for its poor reimbursement to providers) to cover costs, it is even more unreasonable to put measures into place which would increase staffing requirements and costs for offices providing this treatment. As you may be aware, many physicians prefer not to treat addiction at all, as patients with addiction are seen as undesirable or dangerous by the public and even by many educated professionals. It is very difficult to recruit physicians into this line of work, and onerous regulations would almost certainly push away any physician who is "on the fence" about providing this treatment.

I understand that it is unlikely that, based on my letter, the rule will be scrapped in favor of a small number of simple to understand provisions. As such, I have signed on to a document authored by Dr. Paula Taylor and supported by Drs. Brad Hall, Ahmed Faheem, and C. Rollynn Sullivan which should be making its way to your office shortly. I believe that, for the most part, the specific changes put forth in their revision of the proposed rule would make it more workable, though I still believe that many providers will find the length

of the document and complexity of the language intimidating. There is great fear in the medical community in West Virginia around the prescribing of controlled substances, particularly buprenorphine, and, as such, many physicians may deem it too risky to engage in a practice governed by such a complex rule for fear of accidental failure to comply and any associated penalties or professional sanctions. This perception in and of itself may be dangerous, as we may lose sorely needed providers and fail to recruit new ones on the basis of a rule that may be reasonable in and of itself, but appear intimidating.

To summarize, I support efforts to ensure that treatment be therapeutic and never exploitative. I also feel that it is critical that every effort be made to ensure that any regulation is clear and simple and that the utmost priority be given to increasing access to MAT, a life saving treatment.

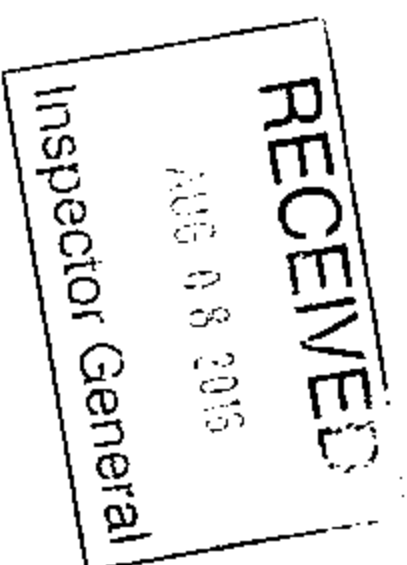
Thank you very much for your consideration.

A handwritten signature in black ink, appearing to read 'Jeffrey M. Richmond', written in a cursive, flowing style.

-Jeffrey M. Richmond, M.D.

Co-Founder of Recovery-Based Outpatient Opioid Treatment Services (R.O.O.T.S.)

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R.O.O.T.S. and Holdings
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M. Katherine Lawson

Inspector General

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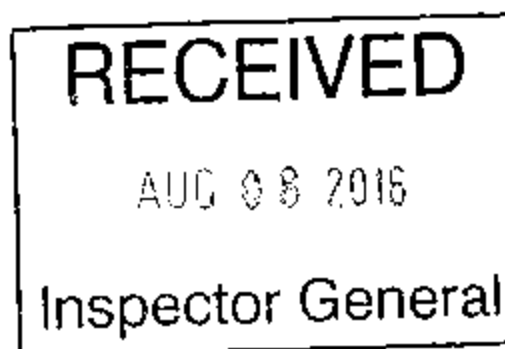
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West Virginia
**Behavioral
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August 5, 2016

M. Katherine Lawson, Inspector General
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RE: Comments on Proposed Rule 69 CSR 12

Dear Kathy:

Please consider the following comments which are being submitted on behalf of the West Virginia Behavioral Health Care Providers Association in regard to Rule 69-CSR-12 *Medication Assisted Treatment –Office Based Medication-Assisted Treatment* which has been put out for public comment. The Association believes strongly that there needs to be regulation of opioid-based medication assisted treatment and that regulations can be developed in a fair and balanced manner. The draft rule released for comment however, is duplicative in nature for many of our members and consequently will lead to both increased costs and decreased access to a badly needed treatment modality.

Association members that provide this treatment option are already licensed by the Office of Health Licensure and Certification (OHFLAC). Yet, there is no recognition of that licensure process and the requirements for behavioral health centers to get their behavioral health license. Senate Bill 454 requires certain items which are also requirements under the existing laws and rules governing behavioral health centers. Instead of recognizing these items the proposed rule requires duplication of efforts which will lead to increase costs. We respectfully request that comprehensive community-based behavioral health centers and other licensed behavioral health centers be waived from all requirements found in the proposed rule that are also requirements of a behavioral health license.

SB 454 sets the requirements and leaves it to the state to determine compliance. If consideration is given to our recommendation, the cost of operating under this rule for the providers will be reduced. State-funded enforcement costs would also decrease.

Also, it appears that the proposed rule does not differentiate between office-based medication-assisted treatment and the existing rules related to methadone treatment. The rule needs to be rewritten to reflect what an OBMAT provider actually does, e.g. our members do not dispense the medication. Nor

should they be required to provide the same level of oversight as is needed for methadone treatment. Our comments attempt to identify all such issues but our general take is that much of the proposed rule is based on the existing methadone rule but that the two are not clinically comparable.

For our members, medication-assisted treatment is but one of many services provided and in fact is a small service in terms of patient volume and revenue generated. Yet the requirements in the proposed rule do not recognize this fact and would mandate certain staffing patterns, hours of operation and provider coverage. Provisions such as these need to be modified or eliminated; otherwise it will no longer be financially viable to provide this service at the expense of other services. A number of our concerns are detailed below but we strongly recommend that the DHHR and Legislative Rule Making Review Committee form a workgroup to more fully address these issues.

There needs to be a balance between regulation, access to care, and cost. The proposed rules as they stand create a regulatory burden that will decrease access to substance abuse treatment; however we believe a workgroup, working diligently, can develop a workable solution that assures accountability and access at a reasonable cost for the provider and more importantly for the state.

The rule regularly refers to days or hours of operation for the OBMAT program. This is clear when the clinic exists only to provide medication assisted treatment, however many providers, including the community mental health centers, operate and provide a variety of services. The proposed rule should be revised to clarify that these operations references only apply when OBMAT services are being provided.

Also, we believe there is a disconnect between the proposed rule and the state's Medicaid program with respect to what Medicaid will pay for and what the rule requires. For example, the rule requires assessments and plans of care to be frequently updated - every 90 days and in some instances more frequently. Medicaid reimburses for such assessments and related planning services at this level of frequency only for "coordinated care" services - MAT is not currently considered such a service. While we understand reimbursement and regulation are two separate items, a more patient-friendly and provider-friendly if DHHR's reimbursement policies and its regulatory policies were as consistent as possible. Changes to the proposed rule should be made to reflect minimum regulatory requirements that are paid for by Medicaid.

The following narrative highlights additional concerns of the Association.

Section 69-12-2. Definitions.

The definition section only incorporates the definitions found in code by reference. We recommend the definitions be inserted into the rule. This makes it easier for businesses operating under a regulation to follow the regulatory framework and better understand the statutory language supporting it.

In particular we believe the following definitions from SB 454, at a minimum, should be included in the regulation:

“Medication-assisted treatment” means the use of medications and drug screens, in combination with counseling and behavioral therapies, to provide a holistic approach to the treatment of substance use disorders.

(This will provide the reader a clearer picture of the legislature’s intention for a program of treatment.)

“Medication-assisted treatment program” means all publicly and privately owned opioid treatment programs and office based medication-assisted treatment programs, which prescribe medication-assisted treatment medications and treat substance use disorders, as those terms are defined in this article.

(This will provide reader with the definition the legislature had for Medication Assisted treatment and will limit confusion.)

“Medication-assisted treatment medication” means any medication that is approved by the United States Food and Drug Administration under section 505 of the Federal Food, Drug and Cosmetic Act, 21 U. S. C. § 355, for use in the treatment of substance use disorders that is an opioid agonist and is listed on the schedule of controlled substances in article two, chapter sixty-a of this code.

(During legislative consideration of this issue the drugs naltrexone and naloxone were excluded from SB 454. Both of these drugs are used for the treatment of opioid addiction but neither contains an opioid and consequently they are not listed on the schedule of controlled drugs. Absent this definition being inserted in the proposed rule we believe the rule could be interpreted by future regulators to include programs which utilize naltrexone and/or naloxone. The proposed rule is addressing medications used in long-term treatment that contain the active ingredient buprenorphine. Including this definition assures legislative intent is followed.)

“Office based medication-assisted treatment” means all publicly or privately owned medication-assisted treatment programs in clinics, facilities, offices or programs that treat individuals with substance use disorders through the prescription, administration or dispensing of a medication-assisted treatment medication in the form of a partial opioid agonist or other medication-assisted medication approved for use in office based medication-assisted treatment setting.

(Including this definition clearly establishes the scope of what the legislature intended to be regulated and will reduce confusion for the reader.)

2.32. Misuse or Non-Medical Use -- All uses of a prescription medication or substance other than those that are directed by a physician and used by an intended patient within the law and the requirements of good medical practice.

We have concern with this definition as it implies that any medication prescribed by anyone other than a doctor is defined as misuse or non-medical use. The legislature, in its most recent session, provided APRNs independent practice authority including the authority to write prescriptions without a collaborative agreement. Currently other providers such as P.A.s and optometrists have certain prescriptive authority. We recommend dropping physician and inserting provider as provided under their scope of practice.

4.2.a. Develop and implement rule and regulations regarding the registration and oversight of OBMAT programs;

We recommend this language be clarified to assure that any rule or regulation developed and implemented go through the legislative rule making process and that passage of this proposed rule as part of a DHHR omnibus rules bill during a legislative session does not provide DHHR the authority to promulgate rules independently of the legislature.

5.3.a. Treatment at the CSU is for no more than 7 days; and

We appreciate the exemption for Crisis Stabilization Units as they are using the drug for detox and not ongoing treatment. In some cases when there is a comorbid disorder it may take longer than 7 days to detox, we would ask that the time limit be increase to 14 days. We support the other qualifiers that are found in the rule as it relates to CSUs.

7.3.e. The medical director shall practice 75 percent of the hours in which the OBMAT program is operating each week in order to ensure regulatory compliance and carry out those duties specifically assigned to the medical director. Nothing in this rule prohibits an OBMAT from designating co-medical directors.

The rule indicates the medical director must practice 75 % of the hours the program operates. In the case of outpatient clinics where MAT is only one component of the services delivered, the 75% requirement should only be applied to the hours of operation for the MAT program itself, and NOT to the hours of operation for the entire clinic for other programs. The use of telehealth should count toward meeting the 75% requirement. Also, if an OBMAT provider is using a third party for counseling this restriction is not workable. The percentage should be tied to the time medical service being provided within the OMBAT program.

7.5.c. Each OBMAT program's policies and procedures shall establish ratios of primary counselors to persons served that are adequate to allow sessions to occur as mandated and that will allow persons served access to a primary counselor, either on site or by referral, but there shall be at least one counselor for every 50 patients in the program.

Legislating staffing requirements sets a dangerous precedent. The legislature has avoided legislating ratios in hospitals, nursing homes and other health providers. We believe the 50 number found in the rule is arbitrary. The key is adequate staffing for the patient base to be served. We would ask that the ratios either be placed in law for all providers or dropped from this rule.

6.5.a.1. The secretary determines that the application is deficient in any respect

The standard of “in any respect” is not a reasonable standard and recommend that this language be re-worded to read “the application is significantly deficient”

7.5.g. An experienced counselor newly employed from another MAT program may be exempt from the mandatory initial training required by this rule, if the program is able to verify and document that mandatory initial training has been received within the previous two years.

We believe that if an individual has met training requirements and that training is documented he/she should be able to work and don’t understand the imposition of the “previous two years” requirement. If they had not switched jobs they could still provide care. We strongly recommend that the above language be changed and further recommend the following:

7.5.g. An experienced counselor newly employed from another MAT program may be exempt from the mandatory initial training required by this rule, if the program is able to verify and document that mandatory initial training has been received ~~within the previous two years~~ previously.

8.1.c.2. The program shall establish procedures for emergency access to dosing information 24 hours a day, seven days a week. This information may be provide via an answering service or other electronic measure. Information needed includes the patient’s last dosing time and date, and dose.

The proposed language is not clear and raises a number of questions. Who are these emergency access procedures for – patients; other MAT physicians; MAT staff? How does this requirement comply with confidentiality requirements? It seems like this is more appropriate for a methadone clinic that actually doses the medication.

8.2.c. The OBMAT program shall document in the patient’s record any rejection of prior authorization, rejection of a submitted claim for written denial from a patient’s insurer or West Virginia Medicaid denying coverage for opioid treatment.

This language should be changed to clarify that clear this is ONLY required if payment will be cash basis, otherwise it is an unneeded. We suggest the following change:

8.2.c. The OBMAT program shall document in the patient’s record any rejection of prior authorization, rejection of a submitted claim for written denial from a patient’s insurer or West Virginia Medicaid denying coverage for opioid treatment if the OBMAT program intends to collect payment on a cash basis.

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

This is not applicable when electronic records are used. These programs are subject to HIPPA and other state and federal privacy laws all records must be kept in a secured manner. We suggest the following language change:

8.3.c. A secure room and lockable equipment for patient records or other appropriate security mechanisms for electronic records;

8.6 Community Relations

This section appears to be written to address the concerns with methadone and note that there are nuisance and zoning laws that deal with what this section wants to accomplish. This will require at least one new staff person and will be expensive. This is not required of physical health and is discriminatory towards mental health, continuing to foster an unfortunate stigma.

8.7 Emergency Preparedness

OMBAT is an outpatient program and does not dispense medication. As with other provisions of the proposed rule, we believe these requirements may be more applicable to methadone programs. The language should be eliminated or altered to reflect the operations of OBMAT programs.

12-9. Facility Construction and Renovations; Life Safety Policies and Procedures

Throughout this section the word “dose” and “administered” appear. OMBAT does not dispense medication. We recommend that sections 9.5 and 9.6 be rewritten to be reflective of what an OMBAT actually does versus, e.g. a methadone Clinic.

12-13. Reports and Records

This section requires a significant number of data reports that need captured and reported by an OMBAT program. We agree that data should be kept and reported however, the required information is excessive. We would ask that a workgroup be established to determine what data is needed to be reported on that will actually be read and acted on. For many of our members the experience has been that data collection and reporting is required in rules but none of it is ever used. Businesses should not be burdened with the cost of unneeded data collection and reporting.

12-16. Medication Security, Storage, Administration and Documentation

This section is another which we believe is not necessary or appropriate for an OBMAT program. The section should be completely rewritten to reflect OBMAT programs do not dispense medication. There needs to be documentation but it needs to be appropriate.

13.2.a.2. The number of patients who have been continually receiving medication-assisted treatment in excess of two years, including the total number of months of treatment for each of these patients;

Our members often do not know and are unable to verify which patients may have received treatment from other providers. This is an even more significant problem in border counties where other state monitoring systems are not integrated with West Virginia’s. Even if the information required in the proposed rule is provided there is no way to validate its accuracy. We would suggest the following:

13.2.a.2. The number of patients who have been continually receiving medication-assisted treatment from the OBMAT provider in excess of two years, including the total number of months of treatment for each of these patients;

13.2.a.7. Statistics demonstrating program compliance with the random drug testing requirements of section 33.6 of this rule;

There is no section 33.6.

16.4.a. Each OBMAT program shall have a procedure through which the patient can discuss dosages of medication he or she receives with appropriate staff members regularly and upon request. This procedure shall be clearly described to the patient during orientation, upon admission and at least annually thereafter. A written explanation of the dosing procedures shall be initialed and dated by the patient and maintained in the patient chart and individualized treatment plan of care.

We believe this proposed language is more applicable for methadone programs given the references to dosages. In an OBMAT program the provider issues a prescription that is filled by the patient at a pharmacy where the pharmacy provides counseling on the medication. We also recommend dropping “and individualized treatment plan of care” from the language. We believe that prescription-related information should be maintained in the patient chart as it is the most up-to-date patient record which eliminates confusion.

16.5. An OBMAT program and its physicians shall not dispense or administer medication-assisted treatment drugs on site.

There may be OBMAT providers that have residential substance programs where providers deliver medication that is prescribed by a doctor and filled by a pharmacy to a resident. The resident self-administers the medication. This prohibition could have significant impact on these residential programs. The language needs to be modified and rewritten to allow these facilities to provide services. In addition, OBMAT providers may also have short term detox programs where they do dispense Buprenorphine. These are short term programs, generally under 30 days, following which the patient is referred to an OBMAT program. The proposed rule should recognize these current programs not negatively impact them with further requirements.

18.1.i. To be given a copy of the initial assessment, written acceptance into the program; or, in the case of denial of admission, a full explanation as to the basis of the denial, and a referral to another OBMAT program based upon the results of the initial assessment;

We recommend adding “upon request” to this provision.

19.7.i. The initial and post-admission individualized treatment plans of care, and any amendments, reviews or changes to the plans;

We recommend changes to this section consistent with Section 25.5

19.7.i. The initial and post-admission individualized treatment strategies or plans of care, and any amendments, reviews or changes to the strategies or plans;

19.7.l. Coordination of care agreements signed by the patient, program physician and primary counselor;

Coordination of care agreements are not currently required when the physician and counselor are employed by the same organization. We recommend the following change:

19.7.l. Coordination of care agreements when applicable signed by the patient, program physician and primary counselor;

19.7.p. Documentation that the patient was provided with a copy of the program's rules and regulations; a copy of the patient's rights and responsibilities; a copy of the detoxification treatment plan option, if applicable; a copy of the patient's individualized treatment plan of care; a copy of the patient's goals; and documentation that each of these items was discussed with the patient;

We would recommend adding "treatment strategy" to this section in order to be consistent with Section 25.5 and recommend the following change:

19.7.p. Documentation that the patient was provided with a copy of the program's rules and regulations; a copy of the patient's rights and responsibilities; a copy of the detoxification treatment plan option, if applicable; a copy of the patient's individualized treatment plan of care or treatment strategy; a copy of the patient's goals; and documentation that each of these items was discussed with the patient.

20.2. Any individual seeking admittance to the OBMAT program shall undergo a pre-admission initial assessment in order to determine whether the person meets the criteria for admission to an OBMAT program. The initial assessment, consisting of a physical examination and an intake screening, shall be conducted by the medical director, an approved program physician or a supervised physician extender. The initial assessment shall focus on the individual's eligibility and need for treatment and shall provide indicators for initial dosage level, if required and if admission is determined appropriate. The determination of admission eligibility shall be made using accepted medical criteria such as those listed in the latest approved version of the Diagnostic and Statistical Manual for Mental Disorders.

The current Medicaid rule allows for non-physician designees to complete the **intake screening** portion of the initial assessment with review and approval by physician. The initial assessment, consisting of a physical examination and an intake screening, shall be conducted by the medical director, and approved by the program physician or a supervised physician extender. We recommend that the proposed rule be changed to reflect that **the intake screening** may be conducted by a non-physician designee but must be reviewed and approved by a physician or supervised physician extender consistent with the Medicaid program rules.

20.21. Patient Transfers.

20.21.a. OBMAT programs shall accept patients transferring from another OBMAT program within the state of West Virginia, if:

20.21.a.1. The OBMAT program accepting a patient voluntarily transferring from another OBMAT program shall provide documentation that the patient's medical record and reasons for the transfer was sought from the patient's previous OBMAT program; and

20.21.a.2. The patient is in compliance with readmission policies for patients who have been administratively detoxified.

Comment: No other medical provider in this state for non-emergent care is required to accept patient transfers. Each program should be allowed to determine if it wants to accept a patient transfer. The physician or program personnel may have just cause to not serve a particular patient. This section should be deleted. It also does not recognize a practice may be full or not taking new patients.

21.2. When practicable, the OBMAT program shall obtain a written consent for release of information from the patient in order to check the records of every OBMAT program within 100 miles of the program site so as to ensure that the patient is not currently enrolled in those programs as well. The request for information may be made by telephone, fax or e-mail. The release of information shall state that only prior admissions may be the subject of inquiry, not contacts without admission. The OBMAT program shall protect patient confidentiality at all times and with all procedures used in acquiring medical or health information.

Unlike Methadone there are a significant number of OBMATs we are not sure how our members check every provider within 100 miles. Also it may be a violation for OBMAT provider to require the release of this type medical information as a condition of treatment. The provider not the state would be subject to liability and federal fines. This is an erroneous requirement, the drug screen will show if the client currently is under treatment.

25.1. Each OBMAT program shall provide adequate medical, counseling, vocational, educational, recovery and other assessment and treatment services. These services must be available onsite at the facility or on a referral basis to outside providers and the medical director at an OBMAT program must be able to document that these services are fully and reasonably available to patients and comply with all federal and state laws, rules and regulations.

Comment: The rule requires an OBMAT program to provide "adequate "vocational, educational" services while these may be needed services for those in recovery, they are not the responsibility of the OBMAT provider to supply these. These are not health services and will probably not be reimbursed by any health payer. We would ask that they be deleted from the rule.

25.5. Within seven days of the admission of a patient, the OBMAT program shall complete a post-admission initial assessment, an initial individualized treatment strategy or plan of care and a coordination of care agreement.

The coordination of care agreement in Behavioral Health industry is currently used when the treating physician and treating counselor do not work in the same agency. We would suggest this language be changed as follows:

25.5 Within seven days of the admission of a patient, the OBMAT program shall complete a post admission initial assessment, an initial individualized treatment strategy or plan of care and a coordination of care agreement, provided a coordination of care agreement is only required when the treating physician and treating counselor work at different agencies/programs.

Section 25.5 allows *for a treatment strategy* or plan of care however throughout the rest of the rule (example 27.2.b) there is no more mention of the treatment strategy in place of the plan of care. We recommend the proposed rule be reviewed to ensure that in all places where a plan of care is mentioned that the option of a treatment strategy be included as well.

25.11. Services provided by an OBMAT program should adhere to recovery initiatives promoted by federal and state laws, rules and regulations and the protocols and guidelines of approved authorities. Recovery initiatives include assistance in overcoming or managing a patient's substance use disorder or other diseases; encouraging a patient to live in a physically and emotionally healthy manner; ensuring that the patient lives in a stable and safe place; engaging the patient in meaningful daily activities, such as job, school, volunteerism, family caretaking or creative endeavors; and assisting the patient in obtaining the independence, income and resources to participate in society and in developing relationships and supportive social networks.

This is a good statement and it is more of a legislative finding than what should be in a regulation. It does not provide specific targets that would guide a provider. This should be the goal, but the rule does not provide a way to measure compliance as such it should be removed or modified.

12-26. Counseling

Counseling should be a part of the process to recovery when using MAT, however the counseling section raises several issues and it should be modified.

We would ask the OHFLAC and BMS sit down on the counseling standards and time frames so that the either the rule mirrors the Medicaid framework or Medicaid follows OHFLAC. Both entities are under the umbrella of DHHR and there should be coordination. For example the counseling time frames in 26.8 do not match what BMS will pay for.

Also if an OBMAT arranges counseling with a third party at separate location from the OMBAT the Medical Director should not be required to be present during that counseling. Maybe the best solution

would be to stipulate the 75% kicks in when OBMAT services that are physical in nature are being performed.

26.7.a. Reflect an appropriate clinical mix of gender, race and ethnicity representative of the population served;

This is a great standard if West Virginia did not have a workforce shortage in this field, the words "to the degree possible based on available staff" should be added.

Section 69-12-27. Provision of Coordination of Patient Care; Post-Admission Assessment and Initial Plan of Care.

12-27. Provision of Coordination of Patient Care; Post-Admission Assessment and Initial Plan of Care.

This section does not reference the use of a treatment strategy.

27.2. Initial Post-Admission Assessments.

27.2.c. The initial post-admission assessment shall consist of a comprehensive medical assessment and include documentation of:

27.2.c.7. A tuberculosis screening;

27.2.c.8. A screening test for syphilis;"

The initial post assessment requires a tuberculosis and syphilis screening. These are tests not often medically necessary or regularly performed by medical personnel during MAT induction. We would ask that both 27.2.c.7 and 27.2.c.8 be removed from the requirements.

28.2.d. Other appropriate and permitted collateral sources.

Not sure what this is?

29.10.a. The coordination of care agreement shall be signed by the patient, program physician and primary counselor. If a change of program physician or primary counselor takes place, a new agreement must be signed.

This is only necessary when these staff persons are NOT employees of the same company.

We would recommend

29.10.a. The coordination of care agreement shall be signed by the patient, program physician and primary counselor when the primary physician and counselor are not employed by the same

company. If a change of program physician or primary counselor takes place, a new agreement must be signed.

33.2.d.3. When using urine as a screening mechanism, all patient drug testing shall be observed

When higher volume urine drug screening is utilized, this may be impractical, yet we don't want to force fewer urine screens if observations cannot be done for all.

We would suggest

33.2.d.3. When using urine as a screening mechanism, at least one random monthly urine drug screen shall be observed

33.2.e.5. Cocaine;

Please add (or metabolites of same)

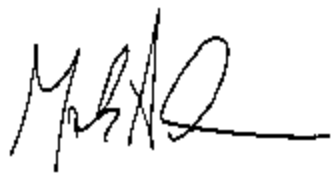
33.2.e.7. Tetrahydrocannabinol, delta-9-tetrahydrocannabinol, dronabinol or other similar substances;

Please add (or metabolites of same)

Also as part of our comment is an attached PDF which compiles the above and includes additional comments from individual members of the association as it relates to this rule.

It is important that the final proposed rule adopt quality treatment standards that will improve the health of West Virginia citizens who need help. In its current form, the proposed rule may become a barrier to treatment. We offer our assistance to help modify the rule in order to develop a workable rule that meets the stated purpose of the legislation without reducing access to needed substance abuse services.

Sincerely,

A handwritten signature in black ink, appearing to read 'MAD', with a long horizontal flourish extending to the right.

Mark A. Drennan
Executive Director

1.1 This legislative rule establishes standards and procedures for the licensure and regulation of medication-assisted treatment – office-based medication-assisted treatment (OBMAT) programs.	Licensure and Regulation of OMB	Comprehensive Behavioral health Centers (CBHCs) are already licensed by OHFLAC. MAT in a CBHC is but one of many treatment alternatives utilized. Many of the MAT draft rules are not consistent with OHFLAC's behavioral health center licensure rules and also are not congruous with BMS' MAT program requirements. It would be impossible for a CBHC to be compliant with these proposed rules while maintaining compliance with the best practice standards adopted by BMS and OHFLAC's behavioral health licensure rules.	Exempt Licensed BHCs from further licensure

6.1

6.1.c. Each OBMAT program location shall be registered separately, regardless of whether the program is operated under the same business name or management as another program.

OBMAT program shall designate a medical director unique to that program. The medical director shall practice at the program and be responsible for the operation of the program in accordance with the requirements of this rule. Nothing within this rule will prevent an OBMAT program from designating

6.1 two co-medical directors Medical Director

Licensure/registration of each site

BHCs with multiple sites already have licenses issued and regulated by OHFLAC

Exempt Licensed BHCs from further registration regulations

BHCs under current licensure regulations do not have to have a Medical Director nor one per site. This places an undue burden on not-for-profit BHCs.

Allow BHCs within their governance policies and procedures to determine direct responsibility for managing its OBMAT Program

7.2.a. The administrator of an OBMAT program shall have at a minimum a bachelor's degree in an appropriate area of study and a minimum of four years of experience in the fields of substance use disorders, behavioral health or health care administration or a master's degree in an appropriate professional area of study and a minimum of two years of experience in the fields of substance use disorders, behavioral health or health care administration; or eight years of experience in the fields of substance use disorders, behavioral health or health care administration.	Administrative Director/Qualifications	May well cause workforce problems due to inability to hire a person that meets these requirements. Not-for-profit BHCs salary ranges do not compete with private agencies.	Reduce experience level required

7.3.e. The medical director shall practice 75 percent of the hours in which the OBMAT program is operating each week in order to ensure regulatory compliance and carry out those duties specifically assigned to the medical director. Nothing in this rule prohibits an OBMAT from designating co-medical directors.		Time Mdirector must spend at site	This was intended to ensure private OBMAT Programs had an actual Medical Provider onsite.	Exempt Licensed not-for-profit BHCs
7.4.d. During all hours of operation, every OBMAT program shall have present and on duty at the program at least one of the following actively-licensed health care professionals:		Staff expected to be present during hours of operation	Smaller county offices of BHCs may have medical staff present/available only during certain days of the week	Include telehealth options for clinic days or crises during non-clinic days
7.4 7.4.d.1. Physician	7.4.d.2. Physician			
7.4 assistant;				
7.4.d.3. Advanced practice registered nurse; or				
7.4 7.4.d.4. Registered nurse.				

7.5.d. Any unlicensed or uncertified counseling staff employed or used on a referral basis by the program shall be directly supervised by a licensed or certified professional or advanced alcohol and drug counselor, or both. At a minimum, the supervisor shall provide at least one hour of supervision per 20 hours of direct service. Supervision may be group in nature, but must consist of case consultation and discussion or clinical training rather than administrative oversight	Supervision requirements of unlicensed counselors	Current licensing requirements do not require BHC counselors to be licensed. Licensed or unlicensed counselors are required to have an hour of supervision once per month unless they are completing requirements for a license, and then the amount of supervision is prescribed by the licensing board.	Allow BHCs to continue to follow rules established by Medicaid/OHFLAC

7.5.h. Counselors with less than one year of full-time experience in the field of substance use disorder treatment and medication-assisted treatment shall accompany an experienced counselor at all times for a minimum of two weeks before seeing persons served without immediate and constant supervision.	Orientation of inexperienced, newly hired counselors	Regulation differs from current licensing/Medicaid rules for BHCs	Exempt BHCs from additional orientation requirements
8.1. Service Operation Schedule	Regulation of hours of operation	Regulations seem pertinent to prescribers of Methadone	Outpatient BHC hours for OBMAT should be less restrictive - not practical for all locations
8.6.a.2.A. Identify program personnel who will function as community relations coordinators and define the goals and procedures of the community relations plan;	Community Relations Coordinators	Seems written for Clinics that prescribe methadone	BHCs do not have a licensing requirement for community relations/exempt BHCs

8.6.a.2.B. Include policies and procedures to resolve community problems, including, but not limited to, patient loitering and medication diversion, to ensure that program operations do not affect community life adversely;
8.6 and

12.12 69-12-12	Waivers and Variances	May grant a waiver	Behavioral Health Centers need to be exempt not a grant, why do we need to report
12.13 69-12-13 13.2.a	Reports and Records	Quarterly Statistical Report	
12.13 69-12-13 13.3.a	Reports and Records	Adverse Incident Reports	Already do this internally
12.13 69-12-13 13.3.d	Reports and Records	Reports have to be reviewed quarterly	too much admin
12.13 69-12-13 13.3.e.2	Reports and Records	prompt investigation	not all incidents require an investigation
12.13 69-12-13 13.3.f	Reports and Records	file a report within 7 days	too much admin
12.13 69-12-13 13.3.h	Reports and Records	A root-cause analysis	too much admin
12.13 69-12-13 13.3.c.5	Reports and Records	harm to family members from ingesting medication	how can we do this?
12.15 69-12-15 15.1.d.3	Risk Management	Individualized treatment plan	can we use strategy instead

12.15	69-12-15 15.1.d.2.A	Risk Management	strength of dosage should decrease over time	conflicts with 15.1.d.4 patient may be maintained on the med as he or she desires
12.15	69-12-15, 15.1.d.3, and other locations	Treatment Plans Med Security, Storage, Admin	Medicaid does not require treatment plans currently at this level of care, quarterly review	
12.16	69-12-16 16.1		Pharmacy does this not us. This applies to OTP dispensing	More for Methadone OBMATs do not dispense omit
12.16	69-12-16	16.1-16.2		omit this is used in OTPs, in OBMATs clients discuss this at their appts. as needed and it is documented in the note.
12.16		16.4.a	dosing forms	
12.16			Rx info is it necessary to require dx, data 2000 and 16.7 OBMAT license number?	remove dx, data 2000 and OBMAT license number needs to say tx plan or tx strategy
12.16		17.1.c	tx plan	
12.16		17.1.g	outcomes monitoring	this can be done and some of these outcomes are already in place, however, it still looks very much like OTP, refine outcomes specific to OBMAT

12.16		additional quality improvement outcomes	17.3 studies by state oversight	Need to know specifically what the outcomes measured would be to see if we have the capability to collect data requested.
12.16	17.4b.	DCP and tracking		Currently we call clients in for random medication counts to ensure they are taking medication correctly, have the correct amt., etc., what would help is if the pharmacies in the state were required to list the numbers on each film package distributed to help ensure the meds brought for counts are the clients.
12.16				For tracking it is documented in the client's chart if there has been any diversion etc., is a separate log really necessary?
12.16	18.1.c	Individualized plan of care		Diversion is typically grounds for D/C. again needs to also say tx strategy

12.16	18.1.d	schedule to receive medications	Currently we have adopted the Medicaid guidelines of time in tx and progress for how often they are seen to receive their tx, i.e., weekly, bi-weekly, etc. would that not work to continue in that way?
12.18 §69-12-18. Patient Rights.	18.1.i. To be given a copy of the initial assessment, written acceptance into the program; or, in the case of denial of admission, a full explanation as to the basis of the denial, and a referral to another OBMAT program based upon the results of the initial assessment;		18.1.i. To be given a copy, upon request, of the initial assessment, written acceptance into the program; or, in the case of denial of admission, a full explanation as to the basis of the denial, and a referral to another OBMAT program based upon the results of the initial assessment;
12.18 69-12-18 18.1.i.	Patient Rights	Given a copy of their assessment	They can request for a copy
§69-12-19. Patient Records.	19.7.i. The initial and post-admission individualized treatment plans of care, and any amendments, reviews or changes to the plans;		19.7.i. The initial and post-admission individualized treatment strategies or plans of care, and any amendments, reviews or changes to the strategies or plans;

12.19	19.7.l. Coordination of care agreements signed by the patient, program physician and primary counselor;	Coordination of care agreements are not required when the physician and counselor are employed by the same organization	19.7.l. Coordination of care agreements when applicable signed by the patient, program physician and primary counselor;
12.19	19.7.p. Documentation that the patient was provided with a copy of the program's rules and regulations; a copy of the patient's rights and responsibilities; a copy of the detoxification treatment plan option, if applicable; a copy of the patient's individualized treatment plan of care; a copy of the patient's goals; and documentation that each of these items was discussed with the patient;	if a treatment strategy is in place and a formal treatment plan is not required, these items may not be applicable	19.7.p. Documentation that the patient was provided with a copy of the program's rules and regulations; a copy of the patient's rights and responsibilities; a copy of the detoxification treatment plan option, if applicable; a copy of the patient's individualized treatment plan of care, when applicable; a copy of the patient's goals, when applicable; and documentation that each of these items was discussed with the patient;
12.19 69-12-1919.7.8	Patient Records	assessments completed every 90 days	Goes against Medicaid requirements
12.19 69-12-19, 19.7.e	physical and biopsychosocial assessments	Do we need an assessment every 90 days, do we need to be doing physicals?	Physical N/A

12.19 69-12-19, 19.7.l	coordination of care	Currently not needed if all services are done within one agency per Medicaid	follow Medicaid regs
12.19 69-12-19	19.7.c, d and e	initial assessment, biopsychosocial in 30 and every 90	These are OTP requirements, typically in OBMAT we would do a clinical evaluation and then scheduled with the physician. This is then updated annually. Again this is OTP regs, the language is straight out of OTP.
12.19	19.7.i and 19.7.j, 19.7.k	tx plans, Take home medications	Clients in OBMAT have tx strategies or treatment plans dependent upon what all services are appropriate, OTPs do a tx plan on every client.
12.19			again this is OTP, in OTP that is necessary because they would not be on a BOP due to not getting an rx, however, OBMAT utilizes BOP because they would be getting an rx. we currently do an 11 panel uds define community standards
12.19	19.7.m	good faith effort to check dual enrollment screen for substances as determined by community standards	
12.19	20.3g.		

12.19	20.3.i.	check dual enrollment	again the BOP is the best way to do that in OBMAT it would be helpful if all BOPs nationwide were linked, it is difficult if not impossible to check BOP on neighboring states except Ohio which we are currently able to check along with WV
12.19		20.2 Log for non admissions	This is an OTP standard, anyone who is not appropriate for treatment has it documented in their chart. Would this not be sufficient?

		20.2. Any individual seeking admittance to the OBMAT program shall undergo a pre-admission initial assessment in order to determine whether the person meets the criteria for admission to an OBMAT program. The initial assessment, consisting of a physical examination and an intake screening, shall be conducted by the medical director, an approved program physician or a supervised physician extender		The initial assessment, consisting of a physical examination and an intake screening, shall be conducted by the medical director, an approved program physician or a supervised physician extender. The intake screening may be conducted by a non-physician designee but must be reviewed and approved by physician, physician extender
§69-12-20. Pre-Admission Assessment; Admission Criteria and Admission Process.	12.2	69-12-20 20.2	Pre-Admission Assessment	The current Medicaid rule allows for non-physician designees to complete the intake screening portion of the initial assessment with review and approval by physician. includes a physical examination is conducted by the medical director completed a plan of development?
	12.2	69-12-20 20.11.c	Pre-Admission Assessment	Counseling staff should be able to provide the intake same as tx plan?
	12.2	69-12-20 20.16	Pre-Admission Assessment	Induction Phase More for Methadone
	12.2	69-12-20 20.20	Pre-Admission Assessment	Log of non-admissions too much admin
12.2 69-12-2 Definitions		2.20 ITP to tx strategy		tx strategy does not typically include all staff, client and therapist TX strategy for focused level clients and Tx plan for coordinated care clients by definition.

12.2 69-12-2 Definitions		2.22 Indicators for dosage level	typically a clinical eval is done by clinician and then if appears to meet criteria is then scheduled for doctor, therapist does not determine dosage regular outpatient therapy would be intensive individual and intensive group, not an ISP/IOP though.
12.2 69-12-2	2.34 Opioid tx services	clarify intensive services	
12.2 69-12-2	2.40 Plan of Ed	clarify what constitutes Plan of Ed	recommend agency training as part of staff training versus other means, physicians doing MAT have received training, therapists are trained in SA Recommend that this be based perhaps on enrollment, size pf program, for small programs this could be a hardship
12.2 69-12-2	6.1 General Registration Provisions	each office having to have a separate registration versus one registration per agency	
12.2 69-12-2	6.1.d.1	OBMATs do not dispense medications	omit

12.2 69-12-2	6.1.e	Each location shall designate a med director	again hardship fro small programs, for example of an agency has 3 offices and the clients may see the doctor at 1 or 2 of these for the medication review and prescribing but due to work, travel etc., receive therapy only at one of the other offices this creates a hardship and hiring extra medical staff that would not be necessary
12.2	6.4a	initial registration	Is there to be no grandfathering?
12.2	6.4.c.1 initial registration	12 months at a time	suggest 36 months at a time
12.2	6.4.c.3 renewals	12 months at a time	suggest 36 months at a time
12.2	6.3.a.3 renewal fee	500.00 plus adjustment	suggest 250.00
			these seem more like OTP dispensing clinic requirements rather than OBMAT which might continue to be better served under the Behavioral Health Licensure as it has been when no dispensing is involved.
12.2	6.5.a.2	state and federal standards	

12.2 69-12-2	Definitions	Medication Assisted Treatment is not defined. The rule as written appears to regulate any program which administers any medication in the treatment of opioid dependence - such as Vivitrol, Catapres, anti-emetics, etc.	Limit Medication Assisted Treatment to the administration of opiate-like drugs for the purpose of treatment of opioid dependence.
12.21 69-12-21 21.2	Multiple Program Enrollments	check for other program involvement	Time-consuming
12.21 69-12-21	21.1 tx at other facilities	currently a client has the right to seek MAT at a treating physician and receive therapy at any agency of their choice, they only receive meds at one practice but are free to seek therapy where they choose, therefore it would be difficult to enforce this. Again this is an OTP reg for clients getting dosed not getting an rx	clarify that this would be receive a prescription for MAT at only one program.
12.21	21.2 checking within 100 mile radius		checked currently through BOP

12.21	24.1 orientation	this language is again from OTP	clients currently sign an agreement to treatment after having the clinical evaluation and being seen by physician and prior to prescription being given, this consent to tx has the client signature stating that they agree to the rules of the program, this is also reviewed in their assessment for treatment.
12.21		24.5 orientation	Again done in OTPs, agreement for treatment along with client handbook covers all these items. for clients needing to address theses types of issues referral would be most appropriate, clinical eval at intake and annually
12.21		25.1 vocational, education, etc.	
12.21		25.4 Biopsychosocial q 90 days	
12.21	25.10.b	clarify agreement?	
12.21		26.2 individual plan of care	needs to be tx strategy or tx plan for small programs this would be difficult to manage
12.21		26.5 same sex csftrs.	

12.21		26.8 frequency of cslg.	this would be the minimum program could require more correct?
12.21		tx plans, Take home	tx plans or treatment strategy
12.21		27.1 medications	this is for coordinated care need to state tx plan or tx strategy
12.21	27.2.b	plan of care within 7 days	if going to be required referred out to PCP or health dept.?
12.21	27.2.c.7-27.2.c.11	required medical testing	
12.21	27.2.c.18	medical tests, exams	again referral to PCP or health dept. we did not have the ability to do EKGs, Pap smear etc. in our OBMAT offices we are a behavioral health facility
12.21	27.2.d	physical assessment q 90 days	clarify physician assessing for stability in MAT or performing duties of a GP?
12.21	27.2.f.3	w/in 27 days	if client does not comply with this then are we required to d/c?
12.21	27.3.a.1	f/up physicals	clarify actually physical exam as like a GP or to evaluate for stability in MAT?
12.21		27.4 Initial plan of care	Again tx strategies are used for clients that do not need coordinated care

12.21	69-12-28	Physicals	I don't know that any client's insurance is going to approve and cover a physical that occurs at 30 days and then every 90 days thereafter if you are meaning a full physical, clarify?
12.21	69-12-29	Individualized tx plan of care	Again this would only be for coordinated care clients not all will qualify for this
12.21			These continue to appear to be OTP standards This is documented in client chart notes why would we need to separate form again this is done in OTP
12.21	29.8.b	discuss MSW	
12.21	29.8.f	re-entry in good standing	this would also need to consider that there would be an pending in the program at the time the client wished to do so or referral would be needed.
12.21	29.10.c.5	medications and dosage	as this can change we would have to sign a new one more than annually, this is typically documented in the chart.

12.21	29.10.c.6-7	rx hx coordination of care agreement	this would be in the client documentation not on the agreement for care currently is one we use from Medicaid
12.21	29.10.d		
12.21	30.9.b	higher stabilizing dose	what would this dose be? as they arise or prior to situation presenting itself? Typically in OTP they would bring them to dose, but OBMAT is a rx is the prison going to fill the rx for them?
12.21		30.1 cooperative agreements	this is OTP language not OBMAT
12.21	30.11.b	take homes	OBMAT is a prescription program, we do not dispense.
12.21	30.12.c	no take homes for 30 days	
12.21	30.12.c.2-30.12.c.4	Again this is all OTP it does not apply to an OBMAT	omit seems more OTP than OBMAT
12.21	30.13.c	amt. of sessions	
12.21		2 years then detox unless 30.14 doc continues	earlier in this document it states that as long in compliance client can stay indefinitely must clarify which way it is going to be this document states both.

			CLIA waived facilities staff have training on doing dip tests and send out any positives for confirmation all would not need set out. In cases where the client admits to use on positive dip there is no reason to send out.
12.21	33.2.a	outside labs only	
12.21	33.3.b.4	states 4th illicit d/c	still have ability to be more stringent, 3 versus 4 can decrease amt. of days
12.21	33.3.c	refers to the OTP language of rx	
	25.5. Within seven days of the admission of a patient, the OBMAT program shall complete a post-admission initial assessment, an initial individualized treatment strategy or plan of care and a coordination of care agreement.	The coordination of care agreement is currently used when the treating physician and treating counselor do not work in the same agency.	Within seven days of the admission of a patient, the OBMAT program shall complete a post-admission initial assessment, an initial individualized treatment strategy or plan of care and a coordination of care agreement. A coordination of care agreement is only required when the treating physician and treating counselor work at different agencies/programs.
	§69-12-25. Required Services.		
	12.25		

		25.5. Within seven days of the admission of a patient, the OBMAT program shall complete a post-admission initial assessment, an initial individualized treatment strategy or plan of care and a coordination of care agreement.	Section 25.5 allows for a treatment strategy or plan of care however throughout the rest of the rule (example 27.2.b) there is no more mention of the treatment strategy in place of the plan of care. must provide or refer to prenatal care	In all places where a plan of care is mentioned there should also include the option of a treatment strategy in it's place. We cannot provide--would need to refer.
§69-12-25. Required Services.	12.25	69-12-25 25.8	Required Services	
	69-12-25, 25.4 * and other locations	12.25	Physical examination	Will agencies be required to do a phsyical exam on top of a pshycatric one? And every 90 days? transmission of HIV, Hepatitis should be eliminated
	69-12-26 26.4.a	12.26	Counseling	Medicaid won't reimburse
	69-12-26 26.4.b	12.26	Counseling	Domestic Violence Medicaid won't reimburse
	69-12-26 26.5	12.26	Counseling	Same sex counselors Hard to do due to work force issues
	69-12-26 26.8.a-c	12.26	Counseling	Counseling times Inconsistent with Medicaid Regs
	69-12-26, 26.8	12.26	Counseling sessions	Counseling sessions are not in line with current Medicaid standards, also difficult to track

	27.2. Initial Post-Admission Assessments.		
	27.2.c. The initial post-admission assessment shall consist of a comprehensive medical assessment and include documentation of:	The initial post assessment requires a tuberculosis and syphilis screening. These are tests not often medically necessary or regularly performed by medical personnel during MAT induction.	remove the requirement for tuberculosis and syphilis screenings as part of the post admission assessment.
§69-12-27. Provision of Coordination of Patient Care; Post-Admission Assessment and Initial Plan	27.2.c.7. A tuberculosis screening;		
12.27 of Care.	27.2.c.8. A screening test for syphilis;		
	6.5.a.1. The secretary determines that the application is deficient in any respect		should this read 'the application is signi
12.27			
	7.5.g. An experienced counselor newly employed from another MAT program may be exempt from the mandatory initial training required by this rule, if the program is able to verify and document that mandatory initial training has been received within the previous two years.	7.5.g. An experienced counselor newly employed from another MAT program may be exempt from the mandatory initial training required by this rule, if the program is able to verify and document that mandatory initial training has been received within the previous two years— previously.	
12.27			

12.27	8.1.c.2. The program shall establish procedures for emergency access to dosing information 24 hours a day, seven days a week. This information may be provide via an answering service or other electronic measure. Information needed includes the patient's last dosing time and date, and dose.	It is not clear WHO these emergency access procedures are for. Are they for other MAT physicians? Emergency rooms? The patient? MAT staff? How does this requiremetn comply with confidentiality requirements?	
12.27	8.2.c. The OBMAT program shall document in the patient's record any rejection of prior authorization, rejection of a submitted claim for written denial from a patient's insurer or West Virginia Medicaid denying coverage for opioid treatment.	Need to make clear this is ONLY if payment will be cash basis, otherwise it is an unneeded.	8.2.c. The OBMAT program shall document in the patient's record any rejection of prior authorization, rejection of a submitted claim for written denial from a patient's insurer or West Virginia Medicaid denying coverage for opioid treatment if the OBMAT program intends to collect payment on a cash basis

12.27	8.3.c. A secure room and lockable equipment for patient records;	This is not applicable when electronic records are used.	8.3.c. A secure room and lockable equipment for patient records or other appropriate security mechanisms for electronic records;
12.27	13.2.a.2. The number of patients who have been continually receiving medication-assisted treatment in excess of two years, including the total number of months of treatment for each of these patients;	We cannot know who may have received treatment from other providers	13.2.a.2. The number of patients who have been continually receiving medication-assisted treatment from the OBTAIN provider in excess of two years, including the total number of months of treatment for each of these patients;
12.27	13.2.a.7. Statistics demonstrating program compliance with the random drug testing requirements of section 33.6 of this rule;	There is no section 33.6	section 33
12.27	33.2.d.3. When using urine as a screening mechanism, all patient drug testing shall be observed	When higher volume urine drug screening is utilized, this may be impractical, yet we don't want to force fewer urinal screens if observations cannot be done for all.	33.2.d.3. When using urine as a screening mechanism, at least one random monthly urine drug screen shall be observed

12.27	33.2.e.5. Cocaine; 33.2.e.7. Tetrahydrocannabinol, delta-9- tetrahydrocannabinol, dronabinol or other similar substances; or	(or metabolites of same)
12.27		(or metabolites of same)

12.27	16.4.a. Each OBMAT program shall have a procedure through which the patient can discuss dosages of medication he or she receives with appropriate staff members regularly and upon request. This procedure shall be clearly described to the patient during orientation, upon admission and at least annually thereafter. A written explanation of the dosing procedures shall be initialed and dated by the patient and maintained in the patient chart and individualized treatment plan of care.	16.4.a. Each OBMAT program shall have a procedure through which the patient can discuss dosages of medication he or she receives with appropriate staff members regularly and upon request. This procedure shall be clearly described to the patient during orientation, upon admission and at least annually thereafter. A written explanation of the dosing procedures shall be initialed and dated by the patient and maintained in the patient chart and individualized treatment plan of care.

12.27	16.5. An OBMAT program and its physicians shall not dispense or administer medication-assisted treatment drugs on site.		(This requirement does not apply to Crisis Stabilization Units (CSU) meeting the requirements listed in section 5.)
12.27 69-12-27 27..2.c.7-10	Comprehensive Physical	Screenings	Should be voluntary Tx plan? Focused Care Instead of Coordinated Care
12.27 69-12-27 27.4	Comprehensive Physical	Initial plan of care	
12.28 69-12-28	physical and biopsychosocial assessments	are both needed, can they be done prior to full admission, is a full physical exam necessary Is this in addition to a psychosocial summary completed at time of assessment	
12.28 69-12-28.5	primary counselor reviewing assessment		
12.29 69-12-29	Individualized TX Plan of Care	Master tx plan	Same as above
12.29 69-12-29,29.10	coordination of care	per medicaid coord of care is only needed if one part of the team is outside of the program/agency.	follow medicaid regs

§69-12-29. Individualized 12.29 Treatment Plan of Care.	Requirement for comprehensive treatment plan and review every 90 days	Consumers in low-end outpatient programs are not required to have a treatment plan, and 90 day reviews are not reimbursed generally	Allow BHCs to continue to adhere to Medicaid requirements
12.3 69-12-30	Detoxification Programs	Short and Long Term	Should be able to link to the service if needed
12.3 69-12-30 30.1	Detoxification Programs	program physician provides on site supervision and oversight	We have to offer these?
12.3 69-12-30 30.9.c	Detoxification Programs	maintenance treatment detox prior to	Should be voluntary
12.3 69-12-30 30.10	Detoxification Programs	incarceration	difficult to determine
12.3 69-12-30 30.12.c	Detoxification Programs	takehome meds	More for Methadone
12.3 69-12-30 30.14	Detoxification Programs	maintenance treatment Not all agencies use MAT as part of the crisis detox service	medical necessity issue
12.3 69-12-30	Detox	Most jails and prisons will not continue the administration of MAT medication, staff are usually not notified of incarceration until after the fact	
12.31 69-12-31, 31.4.c	incarceration or other confinement	if positive screens,	
12.33 69-12-33 33.3.b-d	Laboratory Services	increased counseling	workforce issues

12.33 69-12-33, 33.2.d.3	observed drug screens	Some agencies do not do observed drug screens	should be optional should be included as this drug is not currently legal in WV
12.33 69-12-33, 33.3.c	THC	Not a drug?	
12.34 69-12-34	34.2.d	uses tx plans language	needs tx strategy clarified if on both or only tx plans
12.34	34.4.b	MAT and pain management	if the client is prescribed and opiate in their pain management clinic current they would not be appropriate to place in MAT this is typically not a service covered by clients funding sources.
12.34	34.5.g	parenting classes	our program is by prescription no medication for MAT is kept on the premises
12.34	36.2.d	drugs on premises	

			We do at times keep patients on suboxone on CSU for more than 7 days especially when the patient has comorbid disorders being treated other than opioid use disorder. In order to accommodate these cases we think extending the 7 day limit is necessary.	
	5.3. Crisis Stabilization Units (CSU) are not required to obtain a state license if the following conditions are met:			
§69-12-5 Certification;	5.3.a. Treatment at the CSU is for no more than 7 days		5.3.a. Treatment at the CSU is for no more than 14 days	
12.5 Approval and Exemptions				

IMPORTANT GENERAL COMMENT: THE RULE REGULARLY REFERS TO DAYS OR HOURS OF OPERATION FOR THE OBMAT PROGRAM. THIS IS CLEAR WHEN THE CLINIC EXISTS ONLY TO PROVIDE MAT SERVICES. HOWEVER, IN MANY CASES (AS WITH COMMUNITY MENTAL HEALTH CENTERS), THE CLINICS OPERATE TO PROVIDE A VARIETY OF SERVICES, ONLY ONE OF WHICH IS OBMAT. IN THESE CASES, THE RULE NEEDS TO CLEARLY INDICATE THE RULE ONLY APPLIES TO THE CLINIC WHEN IT IS DELIVERING OBMAT SERVICES.

12.5			Important general comment: The rule does not recognize OBMAT programs that do not dispense medications on site, but instead provide patients with short term prescriptions for the medication. We need to ensure these types of programs are not required to operate 7 days per week.	The Rule should be clarified to recognize the existence of OBMAT programs that do not dispense medications, and therefore exempted from the 7 days per week operation requirement.
12.6 69-12-6 6.1.c	Registration for OBMAT		We would have to pay for each location?	Exempt Behavioral Health Centers
12.6 69-12-6 6.1.c.1	Registration for OBMAT		We contract for a pharmacy to be on site. They dispense the meds.	This would not apply to us but the pharmacy?
12.6 69-12-6 6.1.e	Registration for OBMAT		Do we have to have a Medical Director per site or just one for Program?	To allow one for Program not for each site.
12.6 69-12-6 6.3.a	Registration for OBMAT		Fees	To have no fees or fees per Program instead of site
69-12-6, 6.1.e/69-12-7, 12.6 7.3+A22	Medical Director		This has to be identified to each site and not an organization	Name medical director for each organization within the state

			The rule indicates the medical director must practice 75 percent of the hours the program operates. In the case of outpatient clinics where MAT is only one component of the services delivered, we need to ensure the 75% requirement is applied only to the hours of operation for the MAT program itself, and NOT to the hours of operation for the entire clinic. We also need to ensure the use of telehealth counts toward meeting this requirement.	The Rule should be clarified to indicate the medical director must be on site 75% of the time "when medication-assisted treatment services are being provided at the site". The rule should also clarify that telemedicine time is counted as in the 75% calculation.
§69-12-7 Administrative Organization and Management of OBMAT 12.7 Programs	7.3.e. The medical director shall practice 75 percent of the hours in which the OBMAT program is operating each week in order to ensure regulatory compliance and carry out those duties specifically assigned to the medical director. Nothing in this rule prohibits an OBMAT from designating co-medical directors.			
12.7 69-12-7 7.2	Admin Organization & Mgt	This would be a non-billable position but would have to be needed to ensure compliance.	decrease regs	
12.7 69-12-7 7.3.e	Admin Organization & Mgt	Medical Director to practice 75% of hours physician on call at all times	Do not think it needs to be this high.	
12.7 69-12-7 7.4.c	Admin Organization & Mgt		Is this necessary?	
12.7 69-12-7 7.4.d	Admin Organization & Mgt	Must have a physician, or PA, or APRN or RN present during operation.	Not needed if just doing therapy.	

12.7 69-12-7 7.5.c	Admin Organization & Mgt	1-50 counselor ratio	ok
		one hour of supervision to 20 hours of direct service for unlicensed or unsupervised staff.	
12.7 69-12-7 7.5.d	Admin Organization & Mgt		less hours of supervision
12.7 69.12.7 7.5.f	Admin Organization & Mgt	20 hours of initial training two weeks of shadowing	less hours of training
12.7 69.12.7 7.5.h	Admin Organization & Mgt	time	less shadowing time
12.7 69-12-7, 7.2	Program Administrator	This has to be identified to each site and not an organization	Name program administrator for organization Don't have the professional staffing to achieve this, is 1:70 more realistic can these be the same person?
12.7 69-12-7, 7.5c	Counseling staff	1 counselor to every 50 patients medical director and 7.1 program physician	
12.7	7.2.c.5 Security of med storage and safe handling	we do not dispense medication for MAT	omit if physician has DEA X and DATA 2000 is that not sufficient there is no specific guideline of that this is to be?
12.7	7.3.b.3	written plan to obtain competence in SA MAT	
12.7	7.3.c.1	completion of competence plan	

12.7	7.3.c.2.	Probationary period of physician	again I do not see how this is clear of what the training plan must be and who would have already met it other than those docs who have obtained DEA x, DATA 2000, etc. need specifics of what would be required otherwise may be interpreted differently
12.7	7.3.d.5	basic and continuing ed	does this include when therapy is occurring
12.7	7.3.f	present all hours?	
12.7	7.4.d	Present all hours?	again even when therapy is the only service at the specific time being provided? Typically the physician would not have to be present when therapy is provided. will need to know what is acceptable
12.7	7.4.e.3	Plans of education	does this allow for supervision that is contracted outside the agency as well?
12.7	7.5.d	Supervision for licensure	hours should be Mon-Fri only
12.8 69-12-8 8.1.c.1	Environment and Operation	permission to close on Sundays	
12.8 69-12-8 8.1.c.2	Environment and Operation	24 hours a day emergency access for dosing information	More for Methadone

12.8 69-12-8 8.5	Environment and Operation	Infection Control	More for Methadone
12.8 69-12-8 8.5.d	Environment and Operation	Infection Control Officer	More for Methadone
12.8 69-12-8 8.6	Environment and Operation	Community Relations	More for Methadone
12.8 69-12-8, 8.2.a, 8.2.c	Insurances	are consumers going to be able to wave their right to billing insurances so that they can private pay? If so that may not clear up the cash clinics	
12.8 69-12-8	8.1.c.1	intent to close on Sundays notice	this applies to OTPs that operate 7 days a week, office based does not
12.8	8.1.c.2	emergency access to dosing info	this applies to OTPs that operate 7 days a week, office based does not, this info would be available through the prescribing pharmacy or by a physician running a BOP
12.8	8.2.c	client requesting that their Medicaid not be billed	this is concerning because I know of no good reason it would not be billed. Concerns the client would pay cash one place and try to go to another and use Medicaid

12.8	8.3.e	private dosing areas	they do not dose at an OBMAT except in induction and that is self-administered
12.8	8.5 Infection control	universal precautions	would the usual universal precautions trainings currently done not suffice?
12.8	8.6 Community Relations	community education/disruptions/diversions	currently call clients at random for medication counts to ensure being taken currently and to decrease diversion, also can check levels if suspicions, again with small clinics there is not an issue with loitering, disruption, we are not an OTP we do not have clients standing in line to dose, we do not dispense in OBMAT
12.8	9.5 Life Safety Policies and Procedures	this section appears to be for OTP	Omit
12.8	13.2.a	reports on clients	This appears to be again related to OTP question if needed in OBMAT?
12.8	13.3.c.1	Again refers to OTP OBMAT does not dispense	Omit
12.8	15.1.d.3	Individualized tx plan	suggest tx strategy or individualized tx plan

12.9 69-12-9 9.5	Construction and Reno	Dosing Reversal of opiate overdose	More for Methadone
12.9 69-12-9 9.5.a.3	Construction and Reno	Currently data required is determined by licensing and Statements of Work from BBHF	More for Methadone Exempt licensed BHCs from additional data required or build into current methods of data provision
13.2. Statistical Reports 13.2 and Records.	Requirement for quarterly statistical reports		
13.2.a. The OBMAT program shall file a quarterly statistical report with the secretary on a form prescribed by the secretary, 18.1			
counselors, psychologists, marriage and family therapists, social workers and other licensed or certified professional care providers comply with the credentialing requirements of their respective professions, obtain and maintain a current license, and complete all continuing education requirements of the licensing board	License requirements for counselors	BHCs do not have a requirement currently that counselors must have licenses to practice	Allow BHCs to continue to follow Medicaid requirements

18.1.c. To receive an individualized treatment plan of care developed according to guidelines established by a nationally recognized authority and approved by the secretary. The individualized treatment plan of care shall include a recovery model, shall be reviewed periodically by the program physician and counselor at OBMAT programs, and shall be maintained in the patient's 18.1 chart;	Requirement for a Treatment Plan and that it be reviewed every 90 days	Currently only Residential Program participants receiving MAT must have a treatment plan; under Medicaid Rehab regulations, those patients seen in lessintensive outpatient modalities have to have a treatment strategy	Allow BHCs to follow Medicaid regulations regarding treatment plans
18.1.i. To be given a copy of the initial assessment, written acceptance into the program; or, in the case of denial of admission, a full explanation as to the basis of the denial, and a referral to another OBMAT program based upon the results of the initial 18.1 assessment; 18.1	Provision of writtenassessment to client	It is usual/customary to provide the written assessment to a client or other entity only upon request and with written consent from the client	Continue current process as is

18.1

19.7.p. Documentation that the patient was provided with a copy of the program's rules and regulations; a copy of the patient's rights and responsibilities; a copy of the detoxification treatment plan option, if applicable; a copy of the patient's individualized treatment plan of care; a copy of the patient's goals; and documentation that each of these items was

18.1 discussed with the patient; Treatment Plan

Medicaid requires that clients in low intensity outpatient programs are required to have a treatment strategy, not a written treatment plan

Continue as required by Medicaid

20.2. Any individual seeking admittance to the OBMAT program shall undergo a pre-admission initial assessment in order to determine whether the person meets the criteria for admission to an OBMAT program. The initial assessment, consisting of a physical examination and an intake screening, shall be conducted by the medical director, an approved program physician or a supervised physician 18.1 extender.

Requirement for initial screening/physical examination

Currently, consumers having an initial assessment for MAT are screened by a qualified, trained clinician. If the consumer meets qualifications for MAT, then a contract is reviewed and signed, lab tests re ordered and the consumer will have a physical examination arranged. Pertinent medical records will be requested. Then, all those results are reviewed by the physician who sees the consumer to determine whether MAT is appropriate.

Allow BHCs to determine patient flow procedures

20.20. Non-admissions. The program shall maintain written logs that identify persons who were considered for admission or initially screened for admission but were not admitted. This log shall identify the reasons why the individuals were not admitted and what referrals were made for them by the program.	Requirements for logging non-admissions	Unless consumer has a record in EMR, tracking produces undue burden on BHCs	Provide exemption for BHCs
19.7.e. All physical and biopsychosocial assessments completed every 90 days; 19.7.l. Coordination of care agreements signed by the patient, program physician and primary counselor;	Requirements for 90day reassessments Coordination of care agreement	Reassessments are reimbursed only due to demonstrated medical necessity Current Coordination of Care Agreement not required for those receiving all services at same agency	If 90 day reassessments are required then payors must reimburse service. Continue requirement as is
26.8. Counseling sessions shall be provided according to generally accepted best practices and shall be offered:	Counseling requirements	Counseling requirements are currently provided to meet Medicaid requirements for MAT	Continue per Medicaid requirements

26.8.a. At least twice
weekly during the first 30
26.8 days of treatment;
26.8.b. At least weekly
during the next 90 days of
26.8 treatment;
26.8.c. At least twice per
month during the
remainder of the first year
26.8 of treatment; and

26.8.d. Thereafter, for
subsequent 90-day periods
of treatment, counseling
sessions shall take place as
needed or indicated in the
patient's individualized
treatment plan of care, but
not less frequently than
monthly as long as the
26.8 patient is compliant.

27.2.d. A program physician or supervised physician extender shall perform a physical assessment of a patient on the same day that the program physician initially prescribes, dispenses or administers a medication-assisted treatment medication to a patient. If the patient continues to be treated for substance use disorder at the program, a physical assessment shall be performed at least every 90 days thereafter. All examinations shall be performed according to accepted and prevailing 27.2 standards for medical care.	Requirement for physical examinations same day as prescription of MAT	Current recommended agency protocol is for physical exam. And lab results to be available to prescribing physician to review for day medication is inducted.	Having results on hand seems to bbe more safe

28.1. Within 30 days after admission, or when the patient is stable and able to fully participate, the program shall complete a physical and biopsychosocial evaluation, or, if an OBMAT program, refer the patient to an outside provider for same, which shall be used to develop the long-term individualized treatment plan of care. The physical and biopsychosocial evaluations shall integrate information obtained in all treatment of the patient at 28.1 the OBMAT program.

29.10. Coordination of 29.1 Care Agreement.	29.10.a. The coordination of care agreement shall be signed by the patient, program physician and primary counselor. If a change of program physician or primary counselor takes place, a new agreement must be signed.	Only necessary when when these staff are NOT employees of the same company.	29.10.a. The coordination of care agreement shall be signed by the patient, program physician and primary counselor when the primary physician and counselor are not employed by the same company. If a change of program physician or primary counselor takes place, a new agreement must be signed.
33.3 33.3.b.4. Upon any subsequent positive drug test within a six month period, the patient may be immediately discharged from the OBMAT program, or, at the option of the patient, may immediately be provided the opportunity to participate in a detoxification plan, followed by immediate discharge from the OBMAT program.	Guidelines for dealing with continued illicit drug use by clients in program	FMRS currently follows SAMHSA and Medicaid guidelines for continued use of illicit drugs by MAT patients	BHCs should follow Medicaid guidelines

§69-12-28. Comprehensive Physical and Biopsychosocial Evaluations	§69-12-28. Comprehensive Physical and Biopsychosocial Evaluations.	Protocols for physical and psychosocial examination within 30 days of admission	Physical and psychosocial completed prior to induction We do not store meds - on site pharmacy does. Licensed BHCs should not have to have additional licenses or reviews other than Medicaid and OhFLAC	Physician should have all needed results to make informed decision regarding appropriate medication dosing This would not apply to us but the pharmacy? Current licenses/reviews for BHCs should be sufficient
12..7	69-12-7 7.2.c.6	Admin Organization & Mgt		
Remainder of	Remainder of Rules	Rules applying to licensing and reviews of OBMAT Programs		
	Section / Sub-Section	Title	Comments	Recommendations

General Comment: The rule throughout requires continued assessments and plans of care being completed every 90 days or more frequently. Currently Medicaid only reimburses for these assessment and planning services at this frequency for "coordinated care" services which MAT currently is not.

Discuss with Medicaid the inclusion of MAT services as a "coordinated care" level service. OR Reduce the frequency of assessment and planning services required to the "focus care" level (once per year).

Archived: Wednesday, August 10, 2016 9:42:15 AM

From: Lawson, Kathy M

Sent: Tuesday, August 09, 2016 11:27:57 AM

To: Rutherford, Jennifer A

Subject: Fwd: Comment for Legislative rule 69-12

Response requested: No

Importance: Normal

Kathy Lawson

Inspector General

Department of Health and

Human Resources

Begin forwarded message:

From: "Pagliaro, Melanie A" <Melanie.A.Pagliaro@wv.gov>

Date: August 9, 2016 at 11:08:55 AM EDT

To: "Lawson, Kathy M" <Kathy.M.Lawson@wv.gov>

Subject: FW: Comment for Legislative rule 69-12

FYI

MELANIE

From: DHHR Secretary

Sent: Tuesday, August 09, 2016 11:07 AM

To: Pagliaro, Melanie A

Subject: FW: Comment for Legislative rule 69-12

This e-mail came to the Cabinet Secretary's web mail box.

Please reply directly to the client with a copy to DHHRSecretary@wv.gov.

Thank you.

Ruth Kemp, Executive Secretary

Office of Deputy Secretary Harold Clifton

304-558-1245

From: Mary Aldred-crouch [<mailto:crouchcounseling@yahoo.com>]

Sent: Saturday, August 06, 2016 7:56 PM

To: DHHR Secretary <dhhrsecretary@wv.gov>

Subject: Comment for Legislative rule 69-12

Hi, I wanted to comment on the proposed Legislative Rule 69-12 open for comment. I have been working in and building programs in Office-Based Medication Assisted Treatment since 2005. I have practiced in licensed behavioral health centers and in FQHCs as well as in Drug Court/Day Report Programs. I also spent 3 1/2 years working for Vickie Jones in BHHF and was the WV State Opioid Treatment Authority, so I am familiar with the older Legislative rule that addressed only OTPs.

Given that President Obama, Secretary Burwell as you as you, our WV Secretary, all have the expressed goal of expanding access to Medication-Assisted Treatment, I think there are two provisions in 69-12 that are counter productive to that goal.

6.1.b A registration is valid only for the persons named and described in the application;

6.1.c Each OBMAT program location shall be registered separately, regardless of whether the program is operated under the same business name or management as another program.

These two provisions require our comprehensive behavioral health providers as well as our federally qualified health centers with multiple locations to draft, submit, monitor and pay for multiple registrations. This is an onerous burden that taxes both

administrative personnel time as well as company finances and will thus dissuade providers rather than inspire them to operate multiple sites.

A second comment I would make surrounds the Program Administrator (section 7.2). The educational requirements listed are not particularly necessary as this is, in my experience, an administrative position. Clinical staff need the behavioral health / addiction background but ancillary staff need organizational and people skills.

Before I go, the description and requirements of the medical director read as if a program will likely need a specifically appointed medical director of the OBOT program as the medical director of the organization may not be the physician responsible for the MAT program. That being said, the designation "Medical Director" may well be redundant in many organizations.

Not knowing exactly where to submit my comments, I send them to you two. Thank you and best regards,

Mary

Mary Aldred-Crouch, MSW, MPH, LICSW, MAC, AADC,
Substance Abuse Services & Behavioral Health Services
Cabin Creek Health Systems
Family Care Health Center

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

CC: Governor of West Virginia

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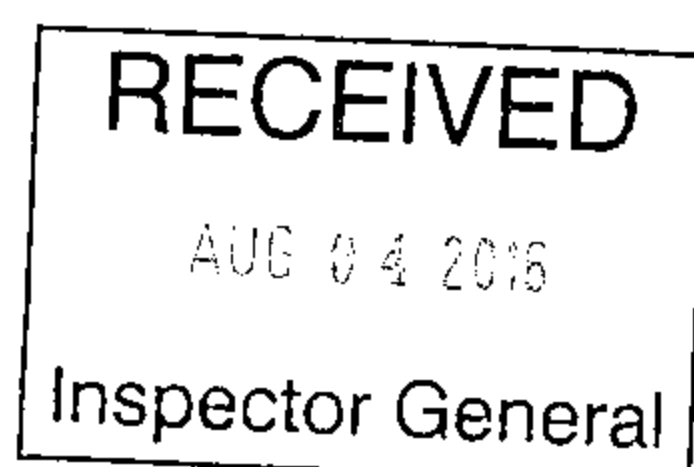
In addition, this law stereotypes individuals suffering from opioid use disorder as disorderly, harassing and unlawful (see: community relations) by requiring doctors to have policies and procedures to "handle medication assisted patients".

Signed: Mon Legg

Tel: 304-618-5210

Address: 265 Shade Creek RD

VICTOR, WV, 25938



To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

CC: Governor of West Virginia

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Signed: *Michael Woodson*

Tel: *304-923-7468*

Address: *8 Ridgview Drive*

Mullens WVa. 25882

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

CC: Governor of West Virginia

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Signed: Brian J. McClellan

Tel: 304-372-4361

Address: 1166 Broad St

Summersville, WV 26651

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

CC: Governor of West Virginia

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Signed: *Jeffrey Campbell*

Tel: *204-589-5703*

Address: *PO Box 53*
Montcalm, WV 26137

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

CC: Governor of West Virginia

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Signed: 

Tel: 708-782-262

Address: 15201 782 N. 630th St
78971

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

CC: Governor of West Virginia

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Signed: _____

Tel: _____

Address: 115 Frontier St.
Beckley, W. Va 25801

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

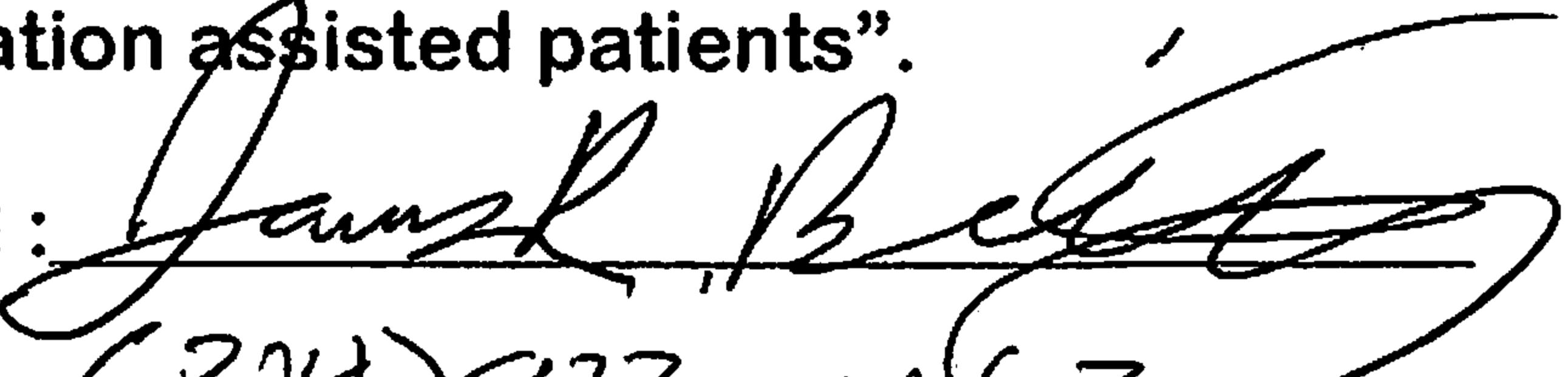
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Signed: 

Tel: (304) 923-0083

Address: 1027 Woodlawn Ave.
Beckley WV 25801

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

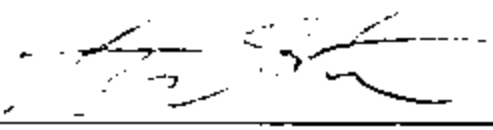
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Signed :  _____

Tel: 304-222-4853

Address: 1277 Rockhouse Rd
Charleston WV 25305

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

CC: Governor of West Virginia

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Signed: Melinda Blankenship

Tel: (304) 923-4113

Address: 1037 Woodlawn

Ave. Beckley W.V.
25801

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

CC: Governor of West Virginia

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Signed: Nick Wilson (Nick Wilson)

Tel: 304-232-2265

Address: P. Saxille

Pineville WV 24874

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

CC: Governor of West Virginia

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Signed: William J. Lewis

Tel: 301-837-5411

Address: 157 McKinney Rd
Stephenson WV 25928

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

CC: Governor of West Virginia

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Signed: Natasha Conley

Tel: 681-238-2547

Address: 164 Lee Court

Parma, WV 25140

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

CC: Governor of West Virginia

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Signed : 

Tel: 304-992-2814

Address: 442 Main St. W. Apt #3
WSS WV 24956

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

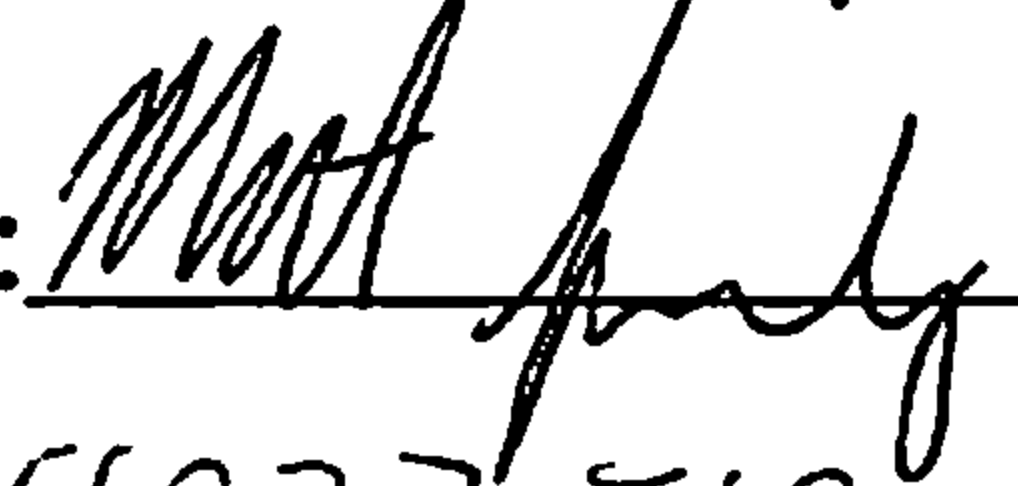
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Signed: 

Tel: 304 237 5120

Address: 104 Sandstone Dr. Apt. #10

Buckley WV 25801

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

CC: Governor of West Virginia

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Signed: Amber R. Coon

Tel: 304-890-2333

Address: P.O. Box 521

Clarksburg WV 24870

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

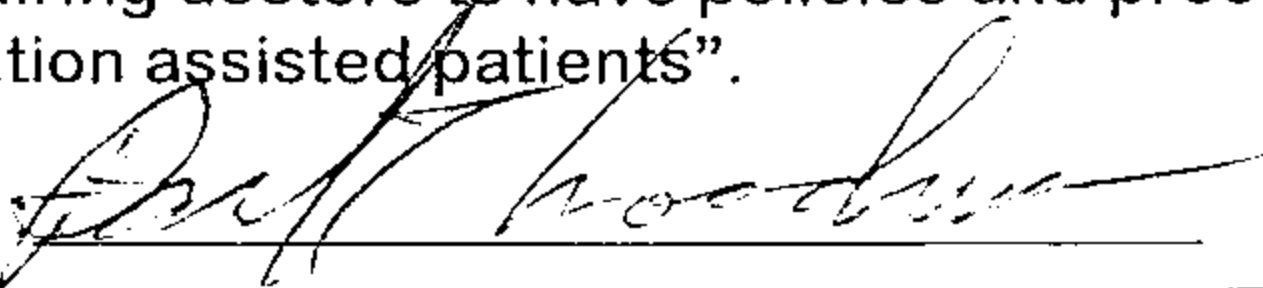
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Signed: 

Tel: 304 766-0765

Address: 402 Mullen Ave.
Hinton, Wd 25951

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

CC: Governor of West Virginia

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Signed : Ketha S F-X

Tel: 304-466-6773

Address: RT 130X 147

Henrietta WV

25951

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

CC: Governor of West Virginia

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Signed: Steve Hall

Tel: (304) 640-8026

Address: 167 Albany Lane

Mount Hope WV 25880

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

CC: Governor of West Virginia

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Signed : Bryan Foltz

Tel: (304) 207-8911

Address: 605 Frantz Avenue
Mullens WV 25882

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

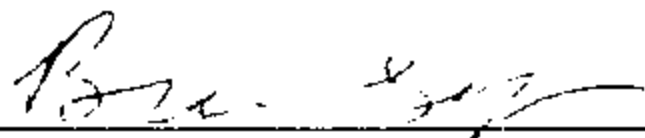
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Signed : 

Tel: 304-938-0755

Address: 891 LCOCK CREEK RD

MISSION VILLE WV, 25320

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

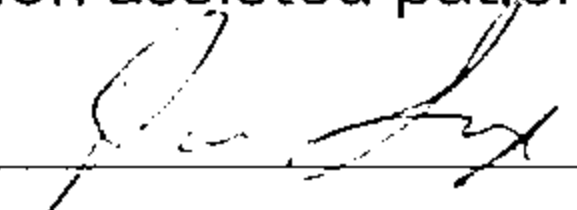
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Signed : 

Tel: 681-422-2303

Address: Box 12

Fayetteville WV 25840

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

CC: Governor of West Virginia

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Signed: Terry Christ

Tel: (81)-220-2146

Address: 104 Houser St
Buckley, WV, 25801

CC: Governor of West Virginia

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In addition, this law stereotypes individuals suffering from opioid use disorder as disorderly, harassing and unlawful (see: community relations) by requiring doctors to have policies and procedures to “handle medication assisted patients”.

Signed: Paula R. [Signature]

Tel: 84-9617

Address: 115 Albany Lane
Albany, N.Y. 12206

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

CC: Governor of West Virginia

The current proposed regulations for Office-Based Medication Assisted Treatment programs are overly cumbersome on providers currently providing services to citizens needing treatment in the State of WV.

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Signed: Morgan Garlin

Tel: 304-619-3099

Address: 190 Nicholas Ave. W
Princeton WV 25962

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

CC: Governor of West Virginia

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Signed: John Rios

Tel: ~~304~~ 681-368-8163

Address: 2029 I-77 Highway

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

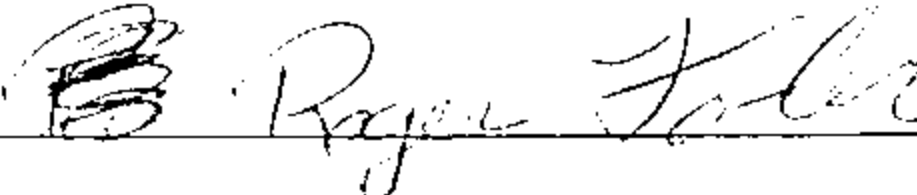
CC: Governor of West Virginia

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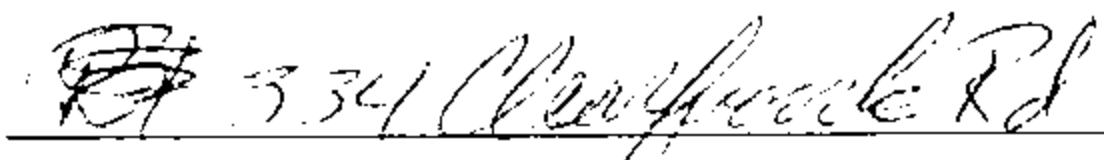
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Signed:  Roger Feller

Tel: (304) 923-3323

Address:  334 Claybrook Rd
Agnew 260

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

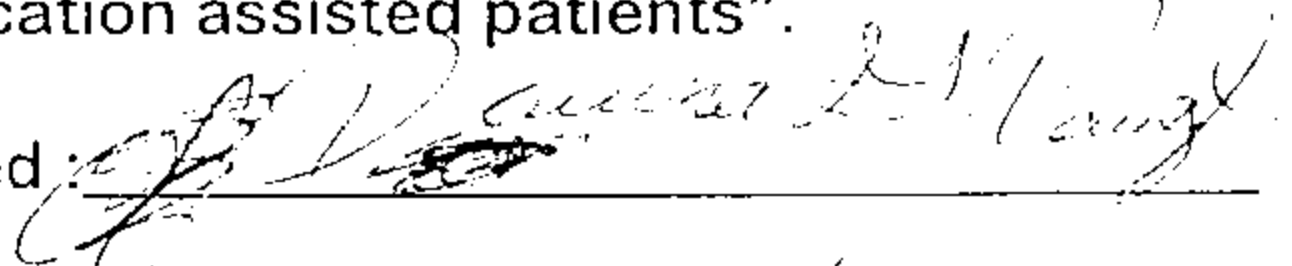
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Signed: 

Tel: (504) 652-5734

Address: 121 Creekside Road

Chapel Hill NC 27514

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

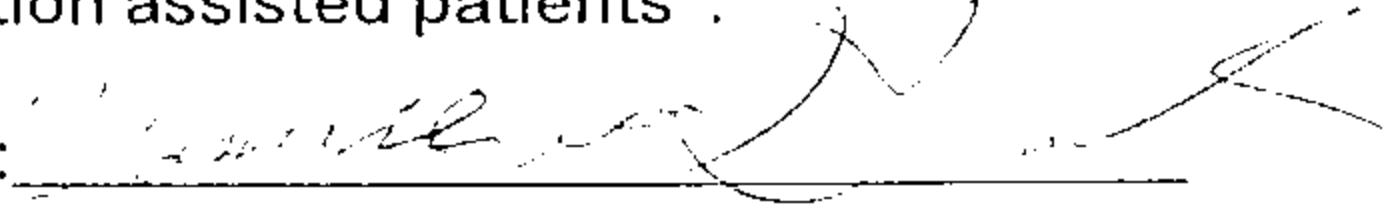
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Signed: 

Tel: 304-266-5734

Address: 1711 Greenbrier St

Charleston WV 25302

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

CC: Governor of West Virginia

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Signed: Sara Martin

Tel: (304) 714-8485

Address: 105 Bellvue Lane

Beckley, WV 25801

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

CC: Governor of West Virginia

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Signed: Betty Hunt

Tel: 681-220-3200

Address: 101 Ashwood St.

Beckley, WV 25801

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

CC: Governor of West Virginia

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Signed: Amy Pawley

Tel: 304-923-5323

Address: PO Box 399

Deanna, WV 24876

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

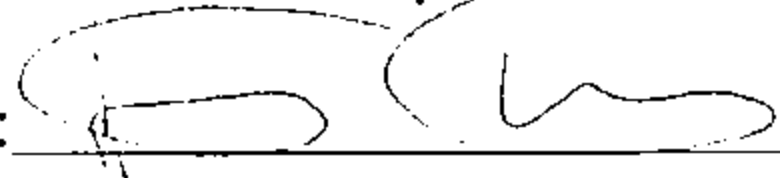
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Signed :  _____

Tel: 304-731-2467

Address: 196 Maple Ave

Apt 27 Oak Hill W.V.

25901

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

CC: Governor of West Virginia

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Signed: Tyrone Harrison Jr.

Tel: 681-220-2080

Address: 402 Temple St

Beckley WV

25801

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

2

CC: Governor of West Virginia

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Signed : William Teller

Tel: 304- 973- 6806

Address: 24 70th St Koppel Station WV

24854

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

2

CC: Governor of West Virginia

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Signed: Jeffrey Coleman

Tel: 504-536-2123

Address: HC 70 Box 723

WSS WV 24936

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

8

CC: Governor of West Virginia

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Signed: Richard Coleman

Tel: 304-576-2123

Address: Hc 70 Box 223

W55 WV 24986

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

3

CC: Governor of West Virginia

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Signed: Donna M. Lambert

Tel: 304-573-5930

Address: 188 Mullens St. (PO Box 905)
Coal City WV 25823

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

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Signed: Justin Dorado

Tel: 832-270-1190

Address: PO Box 262

Pineville WV 24874

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

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Signed: David Calvert

Tel: 304-860-1769

Address: 107 Calloway St

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

8

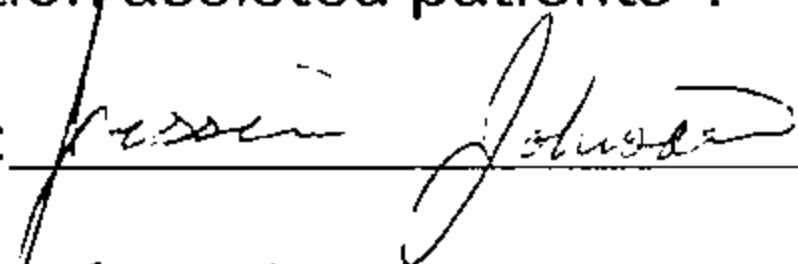
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Signed: 

Tel: 304-872-2959

Address: 504 Woody Ln Summersville

WV 26651

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

2

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Signed: July 13, 2017

Tel: 681-422-8531

Address: 6092 Paint Creek Road

Scarbrough WV 25917

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

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Signed: 

Tel: 304 578-3253

Address: P.O. Box 469

MIDWAY WV 25878

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

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CC: Governor of West Virginia

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Signed: Carol Hise

Tel: 301 445 2374

Address: PO Box 687

Alderson WV 24910

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

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CC: Governor of West Virginia

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Signed: Kelly Gibson

Tel: 304-682-3000

Address: PO Box 1921

Oceana WV 24870

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

CC: Governor of West Virginia

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Signed: Celan Kael

Tel: 304 840-8401

Address: 327 Whitby RD

Coat WV 25915

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

CC: Governor of West Virginia

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Signed: Richard Crum

Tel: 304 992-4497

Address: RT4 Box 17 Rupert WV 25984
175 maple drive

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

CC: Governor of West Virginia

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Signed: Tammy Clark

Tel: 304-992-1174

Address: Rt. 4 Box 17

175 Maple Drive Rupert
25984

To: M. Katherine Lawson, Inspector General
WV DHHR, Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B,
Charleston, WV, 25305

3

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Signed: Greg Smith

Tel: 304 719 6741

Address: 421 Colorado St

Mount Hope WV

25880

Charleston Professional Group, Inc.
1215 Quarrier Street
Charleston, WV 25301
Phone: (304) 344-0349

This is regarding the Proposed Rules for Title 69 Legislative Rule, Department of Health and Human Resources, Series 12: Medication-Assisted Treatment-Office-Based Medication-Assisted Treatment

My name is Rosemary Smith and I am a licensed doctoral-level psychologist in private practice. I have been working in addiction counseling and treatment for 30 years starting as a staff psychologist in 1986 at Charleston Area Medical Center's addiction treatment services for adults and adolescents. I also helped develop Highland Hospital's Dual-Diagnosis Unit in the early 90's. In addition, since 1986, I have worked with patients with substance use disorder on an outpatient basis.

Over the past eight and one-half years, I have treated patients with Opioid Use Disorder: individuals who are prescribed Buprenorphine/ Naloxone. For the past two years I have owned Charleston Professional Group, Inc. (CPG), a practice that exclusively treats patients with addiction disorders. Ralph S. Smith, Jr., MD, and Jerome Massenburg, MD., both board certified psychiatrists, are contracted by my practice. Both physicians have extensive experience treating patients with addictions. They were co-medical directors of a 65 bed unit, Parkside at Charleston Area Medical Center (CAMC), in the 1990's and through the years admitted patients with addiction to other area hospitals.

Patients in our practice are counseled in a group setting format followed by one of the psychiatrists seeing them in a group "med check" format. Approximately 60% of our patients also carry psychiatric co morbidities, such as depression or anxiety. Prior to being treated by CPG, some of our patients had been abusing opioids for 10 to 20 years. Our patients number over 150 and most of them have responded well to the treatment we have provided. Our services are provided at a reasonable cost and are effective. Our patients are stabilized; over 80% of them are now in maintenance. They are gainfully employed, are productive citizens, and have a good life with their families. They require minimal care from us, which consists of monthly group therapy and group "med checks".

The law and this Rule go against the philosophy of the federal government's DATA 2000 statute, which established office-based treatment of opioid addiction using buprenorphine. It was designed simply to treat outpatients in an office environment. It is administered by the Substance Abuse and Mental Health Services Administration (SAMHSA) and oversight is provided by the Drug Enforcement Administration (DEA), who have in fact audited our practice twice and found no deficiencies. The Governor's Bill and particularly this Proposed Rule do not carry forward this philosophy. Private medical practices do not run programs. They treat patients. The Rule is written as if private physician offices employ multiple staff members to fulfill roles such as administrator and community relations coordinator. Ironically, this West Virginia law, which will greatly reduce the number of physicians willing to jump through all the hoops to comply, comes at a time when the federal government, recognizing the need to be able to treat more patients, has just increased the maximum number of patients that a specially

certified physician (either in Addiction Psychiatry or Addiction Medicine) from 100 to 275 patients.

This is a quote from the West Virginia Board of Medicine Position Statement Policy on DATA 2000 And Treatment of Opioid Addiction in the Medical Office "Multiple studies have shown that opioid addiction treatment with buprenorphine can be successfully integrated into office practice by physicians who are not addiction specialists. In such studies, patient outcomes are comparable to or better than outcomes of patients treated in specialized clinics [40-48]." This was adopted from the Federation of State Medical Boards. It gives detailed information about assessment, treatment and monitoring. The whole process focuses on treatment in a physician's office. It was sufficient and detailed enough to guide us before this law was passed. The proposed Rule is onerous, micromanages every aspect of trying to treat these patients and should be streamlined to eliminate the noxious elements.

The law and the Rule do not adequately address the capabilities of psychiatrists, who are able to provide office-based treatment for patients under DATA 2000 by themselves with only a secretary, since they can provide any psychotherapy or counseling needed. That standard should also apply under this Rule.

Many parts of the Proposed Rule will greatly increase costs to patients with little or no clinical indication or benefit. Examples are administrative need for a biopsychosocial assessment and a physical examination every 90 days, need for a quantitative urine drug screen from a certified laboratory when dipstick qualitative technology is accurate, convenient, clinically appropriate and sufficient. Certified laboratory tests cost more than \$100 each. Many of our patients have no health insurance and cannot afford this added needless expense. Additionally, the Proposed Rule utilizes terms and definitions related to Methadone clinics rather than an office-based practice, such as "take home medications", "administered medication", and "interagency agreements", which have no meaning for an office practice.

In our opinion, if parts of the Proposed Rules are implemented, it will force me to close my practice. I suspect this will result in other practitioners ceasing to provide needed services, which will result in hundreds of individuals not getting treatment for their addictions. I fear that many will return to abusing illicit drugs, with concomitant fatalities.

Our other specific concerns with the Proposed Rule are noted below:

2.31. Mental Health Professional -- A person licensed under chapter 30 of the West Virginia Code as a social worker, psychologist or professional counselor.

This section does not mention psychiatrists who are mental health professionals as well as being physicians.

7.2.a. The administrator of an OBMAT program shall have at a minimum a bachelor's degree in an appropriate area of study and a minimum of four years of experience in the fields of substance use disorders...

Physician's offices are not mega-corporations having administrators with such experience. Typically they have an office manager with no bachelor's degree and certainly not four years of experience as described. This regulation is unwieldy and onerous.

7.3.e. The medical director shall practice 75 percent of the hours in which the OBMAT program is operating each week in order to ensure regulatory compliance...

Such a rule will prevent many offices from functioning. There is no clinical or therapeutic reason for this part of the Rule. Regulatory compliance is already provided by the DEA.

7.5.c. Each OBMAT program's policies and procedures shall establish ratios of primary counselors to persons served that are adequate to allow sessions to occur as mandated and that will allow persons served access to a primary counselor, either on site or by referral, but there shall be at least one counselor for every 50 patients in the program.

In office-based practices using the group therapy format, the requirement of one counselor for every 50 patients is not necessary, realistic, or feasible. Needless hiring of additional counselors would greatly increase costs to patients, with no clinical benefit.

8.2.b. Prior to directly billing a patient for any opioid treatment, the OBMAT program must receive either a rejection of prior authorization, or rejection of a submitted claim or a written denial from a patient's insurer or West Virginia Medicaid denying coverage for such treatment.

8.2.c. The OBMAT program shall document in the patient's record any rejection of prior authorization, rejection of a submitted claim for written denial from a patient's insurer or West Virginia Medicaid denying coverage for opioid treatment. The OBMAT program shall also clearly document in the patient's record if the patient has no insurance or has voluntarily and with full knowledge of the financial obligations, including all treatment costs, requested a claim not be submitted to their insurer or West Virginia Medicaid. When any instance described in this section regarding direct billing and acceptance of cash payments from a patient occurs, the OBMAT program shall clearly document in the patient's record the rationale and medical necessity for acceptance into the program.

Sections 8.2.b and 8.2.c are in conflict with each other. Our practice operates on a cash only basis and to purchase billing software for this would be cost prohibitive. Also, most of our patients desire confidentiality from sharing of this sensitive information with their employer or insurer. In addition, it is our understanding that an office is not allowed to have patients pay cash if he/she is on Medicaid and therefore we do not accept patients who are insured through Medicaid.

19.7.e. All physical and biopsychosocial assessments completed every 90 days;

25.4. Each patient accepted for treatment at an OBMAT program shall be assessed including physical and biopsychosocial assessments initially and at least every 90 days following the initial assessment by qualified personnel who shall determine the most appropriate combination of recovery-oriented services and treatment for the patient.

There is no need for physical examinations and biopsychosocial examinations every 90 days for some administrative purpose. These should only be done if clinically indicated. To require every patient to undergo these routinely would increase their cost and serve no medical or therapeutic function.

26.8. Counseling sessions shall be provided according to generally accepted best practices and shall be offered:

26.8.a. At least twice weekly during the first 30 days of treatment;

26.8.b. At least weekly during the next 90 days of treatment;

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

26.8.d. Thereafter, for subsequent 90-day periods of treatment, counseling sessions shall take place as needed or indicated in the patient's individualized treatment plan of care, but not less frequently than monthly as long as the patient is compliant at least twice weekly during the first 30 days of treatment;

The mandated therapy sessions are not feasible for small practices and not clinically indicated. Weekly sessions for the initial six months, biweekly for several months and then monthly have worked well in our practice for many years and resulted in over one hundred patients stable and in maintenance. Mandating the frequency of sessions intrudes onto the doctor-patient relationship and does not allow for individualized treatment plans. It micromanages what we do and how often, even if not clinically indicated.

26.9. The counseling program shall provide for mandatory and documented weekly counseling of any patient who has a positive drug test and is required by this rule to undergo additional counseling. The counseling sessions shall be no less than 30 minutes to a patient with a counselor or other professional as described in section 7.5, whichever is applicable, of this rule who is licensed, certified or enrolled in the process of obtaining licensure, registration or certification. The mandatory counseling sessions may consist of group counseling sessions. However, the patient must attend at least one individual, private session per month.

Mandating individual counseling sessions is not feasible for those practices using the group therapy format and is not needed. The pressures coming from the strength of the group are far more effective in helping patients who have slipped than just meeting one to one with a counselor. Group Therapy has been described as "the definitive treatment for producing

character change," and "the treatment of choice for chemical dependency" (Textbook of Substance Abuse Treatment, 2nd Edition, by Marc Galanter MD, page 370).

27.2.c. The initial post-admission assessment shall consist of a comprehensive medical assessment and include documentation of:

27.2.c.7. A tuberculosis screening;

27.2.c.8. A screening test for syphilis;

27.2.c.9. A hepatitis C test;

27.2.c.10. An HIV test to the extent voluntarily elected by the patient;

28.3.h. Screen for communicable disease and address them as needed...

These tests can be performed by the patient's family physician or health care clinic as needed and are beyond the scope of a small psychological/psychiatric practice.

33.2. Collection and Testing.

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

33.2.b. Each OBMAT program shall have the capability of obtaining medication blood levels when clinically indicated or through random or monthly drug testing of all patients.

Using only certified laboratories for quantitative tests is not clinically indicated and is very expensive for patients (over \$100 per panel of tests). Quantitative tests for buprenorphine are also not useful, since patients may have sufficient blockage of receptor sites for opioids at various blood levels. Each patient will metabolize the medication differently and may need more or less of a dosage. Qualitative tests using dipstick technology can provide sufficient information for clinical purposes in an office-based treatment practice. However, when necessary and clinically indicated, we require patients to provide urine for certified lab testing.

33.2.d.1. A patient receiving medication-assisted treatment medication maintenance services must at least one random drug screen per month during the first year of treatment and random drug screens quarterly thereafter.

We test every patient at every visit. We only bring back patients for a random screen if there is an issue or concern. One random drug screen per month when a patient is being seen only biweekly or monthly would not be clinically indicated, reasonable, or necessary.

33.2.d.3. When using urine as a screening mechanism, all patient drug testing shall be observed to minimize the chance of adulterating or substituting another individual's urine.

Routine observation of urine collection is not indicated or necessary. It is necessary in suspected instances on a case by case basis only and when clinically indicated, not just routinely. Additional staff would be needed to be able to accomplish this administrative task, which would increase the cost to patients.

33.2.e. Drug screenings shall include toxicological analysis for drugs of abuse, including, but not limited to:

33.2.e.4. Benzodiazepines, including testing procedures that detect diazepam, clonazepam, alprazolam and lorazepam;

Determining the type of benzodiazepine would not be necessary for clinical purposes. It is sufficient that we note that the patient is using a benzodiazepine and the treatment plan can then address that adequately.

33.3.b. A positive drug test result after the first six months in an OBMAT program shall result in the following:

33.3.b.1. Upon the first positive drug test result, the OBMAT program shall provide mandatory and documented weekly counseling to the patient of no less than 30 minutes, which shall include weekly meetings with a counselor or other professional as described in section 26.5 of this rule who is licensed, certified or enrolled in the process of obtaining licensure or certification in compliance with the rules on staff at the OBMAT program or by formal referral agreement; and

33.3.b.2. Upon a second positive drug test result within six months of a previous positive drug test result, the OBMAT program shall:

33.3.b.2.A. Provide mandatory and documented weekly counseling to the patient of no less than 30 minutes, which shall include weekly meetings with a counselor or other professional as described in section 26.9 of this rule who is licensed, certified or enrolled in the process of obtaining licensure or certification in compliance with the rules on staff at the OBMAT program; and

33.3.b.2.B. Provide mandatory documented treatment to meetings with the program physician and primary counselor with the patient at OBMAT programs.

33.3.b.3. Upon a third positive drug test result within a period of six months the OBMAT program shall:

33.3.b.3.A. Provide mandatory and documented weekly counseling to the patient of no less than 30 minutes, which shall include weekly meetings with a counselor or other professional as described in section 26.9 of this rule who is licensed, certified or enrolled in the process of obtaining licensure or certification in compliance with the rules on staff at the OBMAT program; or

33.3.b.3.B. Provide mandatory and documented treatment of meetings with the program physician and primary counselor with the patient at OBMAT programs which will include, at a minimum: the need for continuing treatment; a discussion of other treatment alternatives; and the

execution of a contract with the patient advising the patient of discharge for continued positive drug tests.

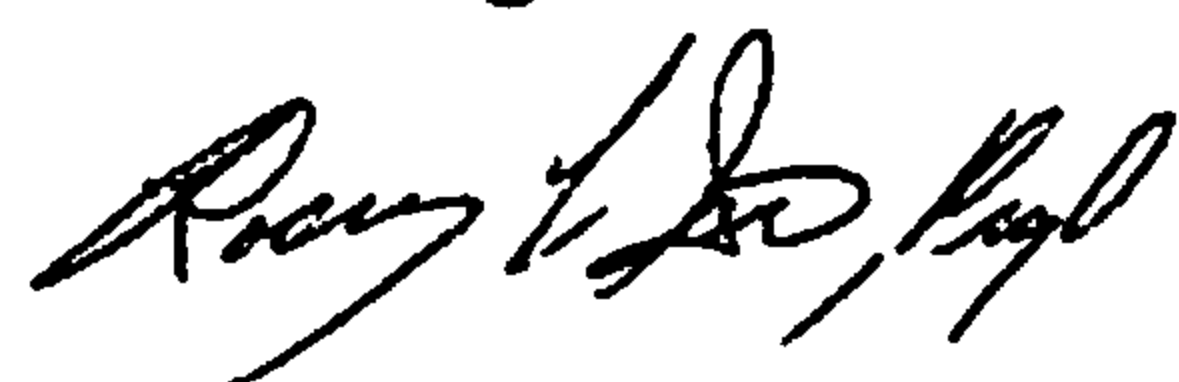
33.3.b.4. Upon any subsequent positive drug test within a six month period, the patient may be immediately discharged from the OBMAT program, or, at the option of the patient, may immediately be provided the opportunity to participate in a detoxification plan, followed by immediate discharge from the OBMAT program. If a patient remains in treatment with the OBMAT programs, the primary counselor and program physician must meet with the patient and revise the individual treatment strategy or plan of care and update the coordination of care agreement.

The mandatory frequency of counseling does not follow clinical guidelines and is not individualized for patients in office-based practices. The requirement of discharging a patient after four positive drug screens is punitive and not therapeutic. Some patients going through crises may have difficulty with multiple slips, yet eventually are able to clean up and be free from drugs with the treatment.

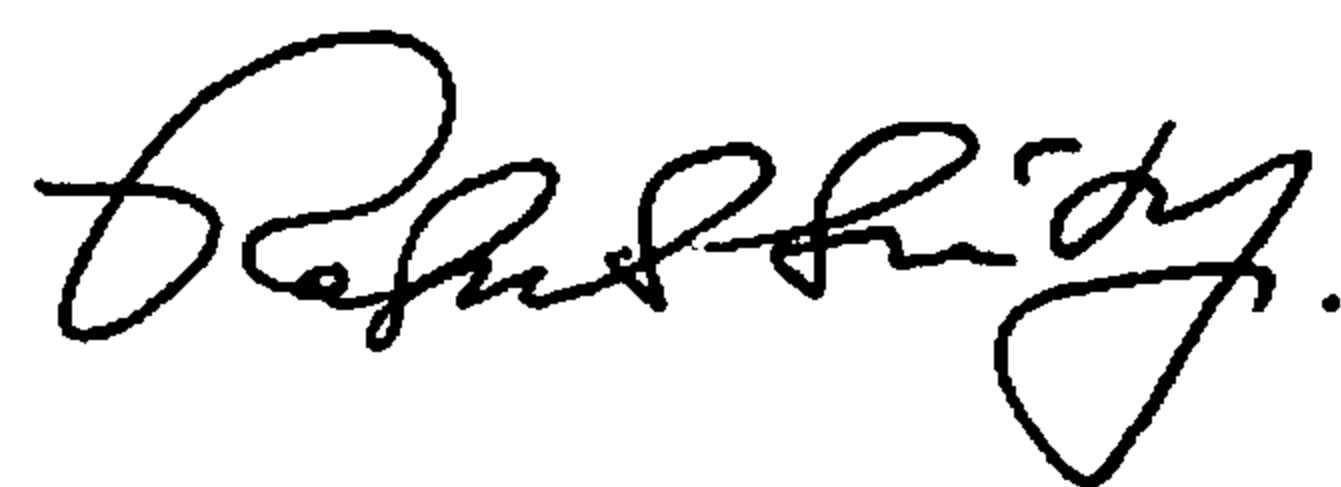
34.6.a. Each OBMAT program shall establish agreements and develop and implement procedures to coordinate with agents of the criminal justice system on behalf of patients insofar as permitted by patient confidentiality requirements.

The criminal justice system has not and will not cooperate with patients on buprenorphine. The Court Clinic system and state probation officers refuse to allow patients to take buprenorphine while in treatment.

We appreciate being able to provide input to these rules. My practice has successfully provided life-saving treatment to many individuals and would like to continue doing so.



Rosemary L. Smith, Psy.D.
Licensed Psychologist
Owner of Charleston Professional Group, Inc.



Ralph S. Smith, Jr., M.D.
Medical Director, Charleston Professional Group, Inc.

Diplomate in Psychiatry, Child Psychiatry, Addiction Psychiatry, and Forensic Psychiatry
American Board of Psychiatry & Neurology, Inc.
Diplomate, American Board of Forensic Psychiatry, Inc.
Diplomate, American Board of Addiction Medicine
Certified, American Society of Addiction Medicine

Certified, American Board of Independent Medical Examiners

Distinguished Life Fellow, American Psychiatric Association
Fellow, American Academy of Child and Adolescent Psychiatry

Manuel Medical Clinic
Ernesto C. Manuel, M.D., F.A.A.F.P.

*Fountain Place Medical Center
300 Prosperity Lane, Suite 201
Logan, West Virginia 25601*

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July 27, 2016

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Inspector General

M. Katherine Lawson
Inspector General
WVDHHR, Office of the Inspector General
State Capital Complex
Building 6, Room 817-B
Charleston, WV 25305

RE: Proposed rules for the operation of Medication Assisted Treatment in Office Based Settings.

Dear Ms. Lawson:

After carefully reviewing the proposed rules, I have come to the conclusion that it is too complex for my solo practice, which focus only on Suboxone Treatment, to continue operation.

Allow me to tell you the genesis of my practice. I was fully employed by Logan General Hospital/Guyan Valley Hospital, now operating under Logan Regional Medical Center, in Logan WV from 1975 until 2010. Six months after retiring, in 2010 it became obvious that Southern WV and neighboring Eastern KY was undergoing massive problems of drug addiction and overdose deaths. In my desire to help I involved myself in OBMAT. By opening clinic and providing Suboxone Treatment we have been able to help change the life of many people in our community. Seeing the transformation of these people, some of which I delivered in the late 70's & 80's, makes me feel good, productive, and as if I have truly made a difference their life.

I opened my clinic for the sole purpose of helping those who had fallen victim to drug addiction. The monetary profit is very little, if any, as I am limited to 100 patients and charge the absolute minimum required to keep the clinic open. The purpose is to extend a helping hand and create a sense of community caring. The life change, for the better for these people is more than enough reward for me.

I am aware that you are doing your best to achieve a solution to existing problems in the state as a whole. Unfortunately the new rules, in particular, the employee requirements, are beyond my reach, unless some waiver or exemptions can be given to clinics like mine that are small, limited, and without violation

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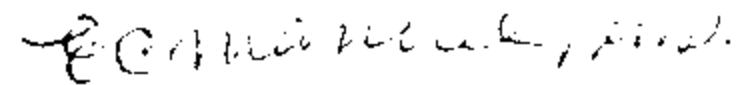
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since the inception, 5 years ago. Without any waiver or other consideration my only option is to cease operation as soon as the new proposed rules are implemented. I have enclosed a copy the rules that would have the most severe impact on my clinic.

Before ending, let me request, if possible, that you offer any help as how to transfer our patients to other approved facilities that will be operating under the proposed new rules, if implemented. Lastly, we ask you to help the several hundreds of people who are currently on our waiting list, wishing to begin treatment. We could provide such list after all privacy issues are cleared.

Thank you for any consideration and understanding that you can extend to our situations.

Respectfully,

A handwritten signature in dark ink, appearing to read "Ernesto C. Manuel, M.D., F.A.A.F.P.", written in a cursive style.

Ernesto C. Manuel, M.D., F.A.A.F.P.

6.5.a.4. The CBMAT program has made arrangements to obtain accreditation, as applicable, from an appropriate agency.

6.5.a.5. The CBMAT program file will have a map as director specifying the program location; or

6.5.a.6. The CBMAT program fails to have an established process for maintaining current, accessible patient records from each participating site.

6.5.b. If the secretary determines not to issue a registration, the secretary shall notify the applicant in writing of the denial and the steps for appeal. Following the denial, the applicant must follow closure procedures in sections 36 and 36.2, if applicable, including notification to existing patients.

6.5.c. An CBMAT program shall surrender an expired, recalled or otherwise invalid registration to the secretary upon written demand.

6.5.d. An CBMAT program may protest the denial of an initial, provisional or renewal registration pursuant to the administrative procedures in section 36.2 of this rule.

6.6. Renewed or Amended Registrations.

6.6.a. The CBMAT program shall submit an application for a renewed registration to the secretary not less than 60 days prior to the expiration of the current registration. After the secretary receives a complete renewal application with the required fee, the existing registration shall not expire until the new registration has been issued or denied.

6.6.b. The program shall notify the secretary 30 days prior to a change in the name, geographic location or services of a program or a change in the principal nature of the CBMAT program and simultaneously shall apply for a registration amendment.

§§ 20-22 7. Administrative Organization and Management of CBMAT Programs.

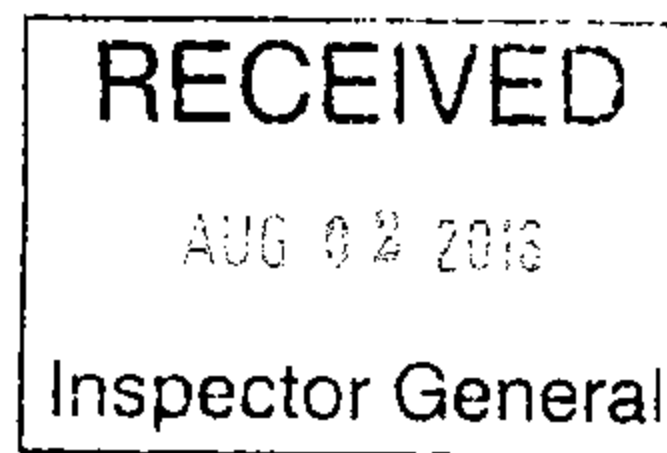
7.1. Each CBMAT program shall identify a program administrator, medical director, program physician(s) and counseling staff.

7.2. Program Administrator

7.2.a. The administrator of an CBMAT program shall have at a minimum a bachelor's degree in an appropriate area of study and a minimum of four years of experience in the fields of substance use disorders, behavioral health or health care administration; or a master's degree in an appropriate professional area of study and a minimum of two years of experience in the fields of substance use disorders, behavioral health or health care administration; or eight years of experience in the fields of substance use disorders, behavioral health or health care administration.

7.2.b. The administrator is responsible for the day-to-day operation of the CBMAT program in a manner consistent with the laws and regulations of the United States Department of Health and Human Services, Drug Enforcement Administration (DEA), and the laws and rules of the state of West Virginia.

7.2.c. Duties of the administrator include:



Ms. Katherine Lawson, Inspector General
WV DHHR
Office of the Inspector General
State Capitol Complex
Building 6, Room 817-B
Charleston, WV 25303

Monday, July 25, 2016

Greetings! My name is Kathleen Chiasson-Downs, and I am a Clinical Therapist at Chestnut Ridge Center, working specifically with our Substance Use Disorder population. I am writing to provide feedback/open comments to the rules of the 69 CSR 12. First, I want to thank you for the time and effort your team has put into creating a unified ruling that will hopefully allow the professionals in WV to come together and provide effective and compassionate treatment to the good people of this state. Second, as a general comment, I'll ask you to really go back and review how much language was brought over from the previous rulings related to OTP/methadone treatment. The Office Based Medication Assisted Treatment we provide here at Chestnut Ridge is different than the traditional methadone treatment, and I believe the countless patients we have that are leading healthy and productive lives would say the same. So, for my comments:

6.3. Registration Fees and Inspection Costs. Are these same fees applied to other clinics that specialize in a particular treatment? This could be seen as a barrier from the get-go, and we want to get *more* providers interested in helping our cause.

7.5.c. A ratio of 50 patients to 1 counselor is nowhere near enough, and I'm wondering what research these numbers are based from. In my current position, I see close to 100 patients within a mix of group therapy and individual therapy, and I can assure you that not only is that caseload manageable, but also I believe I provide effective care to each of those patients. Furthermore, our state does not have nearly enough counselors willing to treat patients with Substance Use Disorders that will fill the need the 50:1 ratio will inevitably require.

69-12-8 and 69-12-9. Facility Construction and Renovations; Life Safety Policies and Procedures. These sections included a lot of language that related to OTP, not OBMAT.

15.1.d.2.A. There is no research that supports this as a clinical recommendation.

19.7.e. I agree that a physical and biopsychosocial assessment is vital to complete at the start of a patient's treatment with us. However, I haven't seen any research that suggests that completing an official biopsychosocial assessment every 90 days is necessary. While in treatment, we are engaging with our patients at every single visit and gathering information on what is taking place for them on a medical, emotional, environmental and spiritual level. So this official assessment is necessary. This is brought up again at **25.4.**

69-12-22. Controlled Substances Monitoring Program Database. I agree that this database is a fantastic resource, however, I take issue with how many times it is mandated for us to check it. We check it

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regularly as well as additionally when we have concern, so please trust us that we will do it when we see fit.

25.2 *and other language related to physical exams.* These examinations don't take place for other mental health diagnoses we see here at Chestnut Ridge, so I don't think it should be different for our OBMAT patients. A biopsychosocial and laboratory work is appropriate and justified.

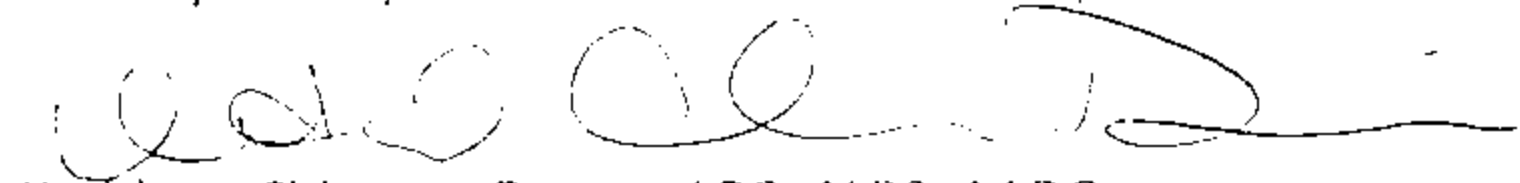
26.8. Requiring twice weekly counseling sessions during the first 30 days is a lot. It's asking a lot of our rural population, who already have a difficult time traveling in once a week for treatment, because each trip in likely includes transportation costs, possible childcare coverage, possible work scheduling issues, etc. You have elsewhere included the language "as clinically indicated," so I would ask for the same respect when we treat our patients during these first 30 days. This ties in to 26.9 as well; when our patients relapse, sometimes we bring them in for additional counseling, sometimes we don't. Making this a mandate takes away the "individualized treatment" that you speak of during 69-12-29 Individualized Treatment Plan of Care.

27.2.c.18...did you really suggest that our patients' assessments include x-rays and a pap smear?

29.8.d. Thank you for including this. Not everyone "gets" the importance of that.

My biggest concern is that amount of structure that is being placed on our treatment providers that is not placed on other treatment providers of other medical diagnoses. For example, **8.6.a.1** discusses the need for our patients not to "act in a manner that would constitute disorderly conduct..." Are these same rules expected of cancer centers, of dentists, of physical therapists? Again, I'm glad we're coming together to create a general standard of care for our patients. But the more and more rules that are included here could mean less individualized treatment, and less providers interested in starting up their own practice.

Thank you for your time and consideration,



Kathleen Chiasson-Downs, LPC, ALPS, AADC
Clinical Therapist
WVU Department of Behavioral Medicine
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Morgantown, WV 26505
kchiasson@hsc.wvu.edu
304-293-7723

"Be kinder than necessary, for everyone you meet is fighting their own battle."

Rutherford, Jennifer A

From: Joseph Saverimuttu <joesav83@gmail.com>
Sent: Friday, August 05, 2016 10:40 AM
To: Lawson, Kathy M
Cc: Calabrese, Debi L
Subject: WV Bill 69-12--Comment

Dear Inspector General Lawson,

I was made aware of the proposed changes in WV Bill 69-12. While I understand the desire for broad legislation to aid in the proper treatment for patients, the rules can hinder those who are providing genuinely good service. I certainly think restrictions can be made on clinics, such as 'pill-mills' utilizing a cash-pay model for patients, as the question becomes, "how did the patient get the cash needed for the treatment?" At times, that patients goes on to sell some of the the prescribed medication at \$35-50, uses those profits to continue treatment, takes enough of the medication to pass a drug screen, and the cycle continues.

CARA likely will help to increase the number of patients receiving treatment, however it doesn't deter or educate those poor performing prescribers. WV Bill 69-12 has a noble mission, however it doesn't enhance direct patient care and it discourages the work of the providers who: pay attention to their patients, are attentive to diversion, and are working to stem the vicious grip of addiction in West Virginian. **Simply put, although well-meaning and written to guide all providers, the disparate impact of the bill restricts the work of our physicians who are our thought-leaders and top performing providers.** Many providers I've worked with across the country are not aware of the long-term affects of the addictive medications they prescribe, are encouraged to speed up the treatment process for efficiency, and are incentivized to improve patient satisfaction--which can results in over prescribing.

My main recommendations are:

- restrictions on clinics that are predominantly/only cash-pay
- guidance on the amount of the drug prescribed and how to titrate the patient down
- full scope review of employment and housing options for patients. Belgium and Portugal have some innovative approaches.
- enhanced support and workforce training services
- utilize research and evidence based tactics to address addiction. Essentially, asking, "has that been successful before?" when a recommendation has been proposed.

Ms. Lawson, thank you for your service and working to improve the lives in our home-state. Please reach out if I can provide further background.

Respectfully submitted,

Joseph Saverimuttu
304.650.6674