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

General Comments

Comment:
We should continue to track patients who expire while in treatment.
Response:
The Department has reviewed this comment. Existing provisions in the rule address this issue adequately and, therefore, no changes were made.

Comment:
The limitations set forth in Rule 69CSR12 restrict a provider's ability to practice evidence-based and scientifically sound medicine in the primary care setting.
Response:
The Department has reviewed these comments. This comment is general in nature and offers no specific amendment.

Comment:
Many of the changes to this rule were brought to OHFLAC during the development of the original rule on behalf of licensed behavioral health providers. Licensed behavioral health providers stated, that including them in this rule was redunant, because the requirements in this rule were already required by 64CSR11 and Medicaid. The rule was created to prevent prescribers from only prescribing medication and not providing the needed therapies. MAT stands for Medication "Assisted" Therapy. It seems changes to this rule are designed to allow non-behavioral health licensed providers to only prescribe medications. This is what placed West Virginia in its current addiction crisis. If we are not careful, in a few years, we will be talking about our MAT drug crisis. Ignoring therapy and only prescribing medications is short sighted and dangerous.
Response:
The Department has reviewed these comments. This comment is general in nature and offers no specific amendment.

Comment:
I encourage the amended version of 69CSR12 to stop singling out females living with active opioid use disorder because of their unique ability to conceive a child. The amended version should also address the fathers of children in utero who are living with active opioid use disorder.
Response:
The Department has reviewed these comments. This comment is general in nature and offers no specific amendment.

Comment:
There needs to be an outlet for primary care physicians to treat opioid addiction in the context of their own practices through MAT. The way the current OBMAT rules are written, it is incentived to build high volume, addiction-specific specialty practices. This is a barrier in and of itself to getting treatment with little evidence that it improve outcomes. It also contributes to the stigma (ie. methadone clinics) and

concentrates people with similar disease/lifestyle issues. We don't isolate people with heart failure or diabetes or hypertension out of primary care and into sub-specialty clinics just because one is harder to manage than another, and we shouldn't do it with addiction medicine either. In primary care we see addiction related disorders every day, and referring out to other providers for treatment fragments care for something that is imminently handled by a PCP. Of course, if the provider isn't interested there is always the option to refer out. I understand there is a strong incentive to make sure that we are doing MAT right and reducing diversion, but I don't know of any evidence that this approach is more effective. I envision a system where a PCP could treat up to 5 or 10 of their own previously established patients with MAT while requiring weekly counseling and/or documented meetings with oversight and reporting requirements to OHFLAC. If there is more interest in this model I would be happy to help draft a concept that would be successful in a primary care 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.

Section 2 Definitions

Comment:

Modify §69-12-2. **Definitions** 2.6 to include Targeted case manager, ~~"the process of coordinating and monitoring the services provided to a patient both within the program and in conjuncture with other providers~~. And Targeted case management services based on §16-SY-2. Definitions.

Add 7.6 to include Targeted Case Management Staff

Add 7.6.1 to include Targeted Case Manager Requirements. (1) A case manager shall:

(a) 1. Have at least a bachelor of arts or science degree in a behavioral science and

(b.) One year of experience in the substance use disorder field

Add 7.6.2. Reimbursement. (1) The department shall reimburse a monthly rate of $334 in total for all targeted case management services provided to a recipient during the month.

(2) to qualify for the reimbursement referenced in subsection (1) of this section, a targeted case management services provider shall provide services to a recipient consisting of at least four (4) targeted case management service contacts including:

(a) At least two (2) face-to-face contacts with the recipient; and

(b) At least two (2) additional contacts which shall be:

1.a. By telephone; or

b. Face-to-face; and

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:

2.11. Counselor – No mention not only of certified addiction counselor – no mention of experience with providing addiction treatment services or supervision of any sort. As vague as this is, could be a BA in elementary education that teaches health classes based on this rule.

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:

2.22 Concerns that the initial assessment is still important to be included to ensure that the client wanting to have an induction into the program is in fact appropriate at least preliminarily to be scheduled for an assessment and induction. The only difference is that the initial assessment done by a clinician would not

make a dose recommendation as this would be the physician recommendation upon induction process. Also concerned that without this initial assessment the client will not have sufficient time to review the program requirements, ask questions prior to starting on medication and then could end up having compliance issues. By having an initial assessment prior to seeing the physician, the client has an opportunity to thoroughly review the treatment and make a fully informed decision.

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:

2.22 Concerns that the initial assessment is still important to be included to ensure that the client wanting to have an induction into the program is in fact appropriate at least preliminarily to be scheduled for an assessment and induction. The only difference is that the initial assessment done by a clinician would not make a dose recommendation as this would be the physician recommendation upon induction process. Also concerned that without this initial assessment the client will not have sufficient time to review the program requirements, ask questions prior to starting on medication and then could end up having compliance issues. By having an initial assessment prior to seeing the physician, the client has an opportunity to thoroughly review the treatment and make a fully informed decision.

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 6 Registration for OBMAT Programs; Fees and Costs

Comment:

Part 6 of the rule has to do with registration for OBMAT programs and outlines the fees that the programs must pay to be registered with the state in order to legally operate. There is the initial registration fee of $250, as well as an annual renewal fee that increases based on the number of patients the facility treats and will be adjusted based on increases in the consumer price index, meaning the renewal fee will likely go up overtime. Dependent on the number of patients being treated, OBMAT programs would pay anywhere from over $500 to over $750 in their first year under this proposed rule. While that may not seem like a large sum to the state, we assure you that it could be reluctant to physicians who want to practice addiction medicine. Family physicians could be reluctant to prescribed buprenorphine because it would increase their malpractice insurance costs by just this amount. There are residency programs that may not be able to allow residents to prescribe because the $700 that is needed to receive a DEA license is more than a resident can afford. For providers in addiction medicine fellowships, who are usually one year out of their residencies, the fees to get a DEA license are a burden. For advanced practitioners, who make approximately the salaries that residents make, these registration and renewal fees would also be a significant financial hurdle. The proposed fee structure within this rule would disincentivize providers from entering this field and give reason for providers already engaged in this practice to discontinue or not increase their patient load. WVSAM and ASAM recommend the state either remove the renewal registration fee entirely or make it uniform and low for all OBMAT programs regardless of their patient loads. In addition, we believe the fines listed under Part 31 detailing penalties and equitable relief could force OBMAT programs to close indefinitely when the infraction could be resolved in an amenable manner to allow them to continue operating. We ask these fines to also be lowered and those that are applied "per day" should instead only be applied at one time.

Response:

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

Comment:
Part 6 also details what OBMAT programs must do if their ownership changes and if they are discovered to be operating without a registration. According to Provision 6.1.6, when program ownership changes, the new owner shall notify the state within 10 days and apply for a new registration. Provision 6.1.12 states that when an inspection reveals a program is operating without a registration, they must apply for one within 10 days. Part 11 outlines plans of correction for OBMAT programs that are found to be in violation of this rule, giving providers 10 days to submit a plan to correct all deficiencies unless a waiver or variance is granted. Part 13 details reports and records, with provision 13.3.5 requiring programs to file a report with the state oversight agency within 7 days to explain how they resolved the incident or adverse event and how they will avoid them in the future. However, when describing the processes the state must adhere to when responding to programs with ownership changes, lack of registration, plans of correction submissions, adverse event reports, or any other correspondence between the program and state, the amount of time the state is allowed to respond is over twice as long as providers have at 30 days. There will be instances where OBMAT providers and programs who violate this rule do so unintentionally or through a clerical error, potentially not realizing they did something wrong until the state contacts them and gives them the short period of a week or a little over to correct the issue, document it, and submit it to the state. This short amount of time to respond to these matters is not enough for providers who are managing large patient caseloads and addressing the complicated disease of addiction. WVSAM and ASAM ask the state to provide some uniformity when requesting OBMAT programs respond to violations, incidents, or state inspections and requests, either giving providers the same amount of time the state has to respond at 30 days or at least half that amount of time at 15 days.
Response:
The Department has reviewed this comment. Existing provisions in the rule address this issue adequately, and, therefore, no changes were made.

Section 7 Administrative Organization and Management of OBMAT Programs

Comment:
Part 7 describes the administrative organization and management of OBMAT programs, explaining what different positions are required to operate the program and what their responsibilities are. Provision 7.5 applies to counseling staff with the requirement that "programs shall assign or make referral to a primary counselor or counseling service for each patient to contribute to the appropriate treatment plan for the patient and to monitor patient progress." WVSAM and ASAM wish to remind the state that in many rural areas there is a lack of not only medical providers trained and waivered to practice addiction medicine, but also psychosocial professionals who can counsel patients. Provision 7.5.4. further states "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." Due to the lack of psychosocial professionals in some rural areas of the state, OBMAT programs may have to hire or refer to higher number of unlicensed or uncertified counselors in order to meet this requirement, thus furthering their workload by now having to ensure a licensed or certified professional is supervising these counselors. WVSAM and ASAM want to bring this issue to the state's attention for consideration of ways to mitigate this extra workload that could be a burden for certain physicians and clinicians practicing in rural areas that may be lacking in licensed or certified psychosocial professionals.
Response:
The Department has reviewed this comment, and no change were made in response. The rule provision is consistent with the requirements of the statute.

Section 8 Environment and Operation

Comment:
8.1.c.2 being removed to provide 24 hour information for health care providers but section 9.3.2 states still must have, (I am assuming by emergency for an MAT client this could also mean a hospital needing to verify does in any emergency situation)?
Response:
The Department has reviewed this comment. Existing provisions in the rule address this issue adequately, and, therefore, no changes were made.

Comment:
8.1.c.2. being removed to provide 24 hour information for health care providers but section 9.3.2 states still must have, (I am assuming by emergency for an MAT client this could also mean a hospital needing to verify dose in any emergency situation)?
Response:
The Department has reviewed this comment. Existing provisions in the rule address this issue adequately, and, therefore, no changes were made.

Comment:
69 CSR 12-8.2. These Statutes would make the OBMAT either decide to submit claims or take cash upon waiver from the patient. The OBMAT is allowed to either offer their own counseling or supervise patients on a referral basis. See "**Each medication-assisted treatment program shall designate counseling staff,** either employee or **those used on a referral-basis by the program**, which meet the requirements of this article and the rules promulgated pursuant to this article." W. Va. Code 16-5Y-5(d) (2017) (Emphasis Added). This allows the OBMAT to submit claims to WV Medicaid and designate (mandate) the use of counseling staff of a non-enrolled but affiliated provider resulting in counseling services which are on a cash only basis. This structure creates the hybrid of Medicaid claims and cash for counseling services. There are a variety of laws that prohibit self-dealing and or kickbacks in healthcare. See Gen. 42 U.S.C. 1395nn or WV Code § 9-7-5(a). The proposed rule currently reads: "The OBMAT Program shall assign or make a referral to a primary counselor or counseling service for each patient to contribute to the appropriate treatment plan for the patient and to monitor patient progress." 69 CSR 12-8.7.5.2. The Medicaid Fraud Control Unit, hereafter MFCU, specifically recommends adding language prohibiting a provider from forcing a patient into an affiliated counseling service where the program and or person in the program has a financial interest unless the program is designating its own counseling staff. The MFCU recommends this to specifically prohibit persons and or corporation from self-dealing while tending to patients seeking rehabilitation form their opioid addictions.
Response:
The Department has reviewed this comment and finds clarification is needed, therefore, changes were made.

Comment:
Unless I am missing something the regulation makes things easier for cash practices to operate than what the statute provides. Instead of requiring a provider to get a denial from insurance, etc. a provider is able to simply have the patient sign a waiver, which opens the process up for abuses and they operate, essentially, like pill mills at that point.
69CSR12-8.2.a goes beyond this and adds the phrase "has voluntarily and with full knowledge of the financial obligations, including all treatment costs, requested a claim not be submitted to their insurer, Medicare, or West Virginia Medicaid."
To my knowledge this additional language is not required by code and based on what I have researched was included in the initial proposed language for the Rule submitted to the SOS on 8/26/2016.
I would request that this language in 8.2.a be removed to simply mirror the requirements of statute.

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

Comment:
Subsection 8.2.1 creates a process allowing for cash payments to OBMATs when they are document in the patient's record. While we support a flexible approach for people who don't have Medicaid and/or are underinsured or uninsured, Jim Matney tells me that he is getting reports of a number of seedy-looking/less than reputable cash only OBMATs popping up around the state, allegedly with lines of people hanging outside the building. While this sounds more like an OTP dispensing methadone rather than an OBMAT doc writing prescriptions out of an office, some fairly knowledgeable folks are relying these concerns to us and we're not totally clear on what mechanisms are available when these likely unregistered fly by night programs pop up. While we recognize that this is a delicate balance, these operators do detract from legitimate providers so it might be helpful to set up some specific publicly posted complaint mechanism for people to use to report such alleged programs to the IG's office when they see one.
Response:
The Department has reviewed this comment and finds clarification is needed, therefore, changes were made.

Section 13 Reports and Records

Comment:
Remove the reporting requirements in 13.2 and 13.3. These reporting requirements are unnecessary and overly burdensome. I support keeping records of adverse events and policies on how to deal with these as part of any routine medical practice. I do not believe it is necessary to report these to the state.
Response:
The Department has reviewed this comment. Existing provisions in the rule address this issue adequately, and, therefore, no changes were made.

Comment:
Remove the reporting requirements in 13.2 and 13.3. these reporting requirements are unnecessary and overly burdensome. I support keeping records of adverse events and policies on how to deal with these as part of any routine medical practice. I do not believe it is necessary to report these to the state.
Response:
The Department has reviewed this comment. Existing provisions in the rule address this issue adequately, and, therefore, no changes were made.

Comment:
13.3.f – appears to be removing requirement for motality report? OBFLAC requires this.
Response:
The Department has reviewed this comment. Existing provisions in the rule address this issue adequately, and, therefore, no changes were made.

Comment:
13.3.f appears to be removing requirement for motality report? OHFLAC requires this. Completion of an orientation for clients has been marked through in some sections, but still stated as required in others. Example: 60.12.23 marked out, 14.4 marked out, but included in 14.3.4 and 17.4-
Response:
The Department has reviewed this comment. Existing provisions in the rule address this issue adequately, and, therefore, no changes were made.

Section14 Staff Training and Credentialing

Comment:
Counselors should be independently licensed, many offices and centers are utilizing unlicensed Counselors.
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:
One area I feel the letter does not address and I would like to share with you is the requirement that all clinical therapists should have or be pursuing their AADC credentialing. While this is of value, it is not the goal for all therapists. We have few therapists through our agency that hold this credentialing or are seeking their supervision for this due to time and treatment of other populations. Throughout graduate school, we are trained in the treatment of substance use disorders and have clinical experience in doing so. I do feel that if this should be changed, then it should be changed to pursuing independent licensure (LICSE or LPC) in the state of West Virginia.
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:
Regulations regarding who can provide group therapy for patient are suffering from addiction needs to be readdressed and more people with counseling experiencing should be allowed to provide this service given that current regulations place a huge burden on providers and there is a shortage of providers for MAT let alone therapy.
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.

Former Section 16 Medication Security, Storage, Administration, and Documentation

Comment:
16.5 use of electronic prescribing removed, however, being able to send to the pharmacy electronically is actually a safer way, no chance of the client losing or misplacing a script or of it getting stolen.
Response:
The Department has reviewed this comment, and no changes were made. Registered providers may create a policy to address this issue.

Comment:
16.5 use of electronic prescribing removed, however, being able to send to the pharmacy electronically is actually a safer way, no chance of the client losing or misplacing a script or of it getting stolen.
Response:
The Department has reviewed this comment, and no changes were made. Registered providers may create a policy to address this issue.

Section 17 Patient Rights

Comment:
17.5 needs clarification that orientation is still requi3ed and strike out was only due to moving it to be included in one area versus multiple. Also "at the earliest opportunity" needs clarification, is this within a week or two weeks, etc. of beginning the program or sooner?
Response:
The Department has reviewed this comment and finds clarification is needed, therefore, changes were made.

Comment:
Completion of an orientation for clients has been marked through in some sections, but still stated as required in others. Example: 60.12.23 marked out, 14.4 marked out, but included in 14.3.4 and 17.4-17.5 just need clarification that orientation is still required and strike out was only due to moving it to be included in one area versus multiple. Also "at the earliest opportunity" needs clarification, is this within a week or two weeks, etc. of beginning the program or sooner?
Response:
The Department has reviewed this comment and finds clarification is needed, therefore, changes were made.

Section 19 Admission Criteria and Admission Process

Comment:
69-12-19.3. "The person desiring medication-assisted treatment must be at least 18 years of age. Exceptions may be made by application with parental consent…" While the exception with consent of a parent is helpful, the treatment is approved by the FDA for patients who are at least 16 years of age. Inasmuch as that age range is the scientific standard, we believe this rule should be changed to "at least 16 years of age…" Additionally, requiring the patient to be at least 18 years of age effectively denies treatment of individuals currently housed in juvenile correctional system and who may benefit greatly from the availability of medication-assisted treatment. For those reasons we request the rule be changed to include patients who are at least 16 years of age.
Response:
The Department has reviewed this comment and finds clarification is needed, therefore, changes were made.

Comment:
Remove 19.3 regarding age requirement. Buprenorphine is approved for patients 16 years and older. The strict requirement of an application to the state opioid treatment authority would limit access to adole scents who acutely need this medication in order to reduce overdose risk and engage in treatment.
Response:
The Department has reviewed this comment and finds clarification is needed, therefore, changes were made.

Comment:
Part 19 regards the admission criteria and admission process for OBMAT programs, with provision 19.3 stating a "patient desiring admission for treatment through the use of a medication-assisted treatment medication must be at least 18 years of age. Exceptions may be made by application with parental consent through the treating physician to the state opioid treatment authority." WVSAM and ASAM recommend this provision be changed to better reflect the approved uses of buprenorphine by the FDA, which allows buprenorphine for addiction treatment to be used by patients 16 and older. We believe the minimum age for treatment admission should be amended without further barrier by having to go through the state opioid treatment authority. Similar to utilization control measures, this process could delay a patient from starting treatment when they present themselves, thus causing them to forgo care entirely or possibly relapsing, which could lead to overdose and death.

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

Comment:
Subsection19.3 creates a rebuttable presumption that patients must be 18+ to access MAT but we are aware of model programs in Ohio and elsewhere serving older adolescents 16+ and buprenorphine is approved for people in that age range. Unfortunately, adolescents, like everyone else in WV, are potentially vulnerable to OUD and we suggest allowing unemancipated minors access to MAY as long as it is clinically indicated with parental consent.
Response:
The Department has reviewed this comment and finds clarification is needed, therefore, changes were made.

Comment:
Remove 19.3 regarding age requirement. Buprenorphine is approved for patients 16 years and older. The strict requirement of an application to the state opioid treatment authority would limit access to adolescents who acutely need this medication in order to reduce overdose risk and engage in treatment.
Response:
The Department has reviewed this comment and finds clarification is needed, therefore, changes were made.

Section 20 Multiple Program Enrollments

Comment:
Need clarification of 20.2, what would be considered when practicable, the Board of Pharmacy is run on all clients, when would it be deemed practicable to check other OTP programs, what mile radius and home many, does this mean OTP clinics only or does this mean any practitioner on the SAMHSA facility locator in the catchment area?
Response:
The Department has reviewed this comment and finds clarification is needed, therefore, changes were made.

Comment:
20.2 Need clarification that 20.2, what would be considered when practicable, the Board of Pharmacy is run on all clients, when would it be deemed practicable to check other OTP programs, what mile radius and home many, does this mean OTP clinics only or does this mean any practitioner on the SAMHSA facility locator in the catchment area?
Response:
The Department has reviewed this comment and finds clarification is needed, therefore, changes were made.

Comment:
Remove 20.2. This is not clear on how a program is to "check the records of opioid treatment programs to ensure that the patient is not currently enrolled in those programs as well." Certainly, this would rarely be practicable on a routine basis. There is no current mechanism to do so. The only way a prescriber would know if a patient has been enrolled in another program is if the patient divulges this information or the medication is listed on the controlled substances monitoring program database.
Response:
The Department has reviewed this comment and finds clarification is needed, therefore, changes were made.

Former Section 20 Initial Assessments; Admission Criteria and Admission Process.

Comment:
Concerns regarding the removal of the 20.5 section as this aids' in ensuring that the appropriate level of care is offered.
Response:
The Department has reviewed this comment, and no change were made in response. The rule provision is consistent with the requirements of the statute.

Comment:
20.5 Concerns regarding the removal of the 20.5 section as this aids' in ensuring that the appropriate level of care is offered.
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 21 Controlled Substances Monitoring Program Database

Comment:
Regulations regarding checking board of pharmacy each visit which could be weekly needs to be readdressed to change to monthly, given that board of pharmacy is not updated quick enough from the time patient fills the medication and sees a provider for the following visit.
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 22 Required Services

Comment:
Remove 22.1. Providing or referring to vocational or educational services, although of value, is beyond the scope of basic best medical practices and beyond accepted MAT guidelines.
Response:
The Department has reviewed this comment and finds clarification is needed, therefore, changes were made.

Comment:
22.3 This states a post admission assessment shall be completed, with no time stipulation so would this now be yearly? Or at what interval, also by clinician or physician? If this if by the clinician still feel that this is most appropriate prior to induction versus post to ensure appropriate level of care.
Response:
The Department has reviewed this comment. Existing provisions in the rule address this issue adequately, and, therefore, no changes were made.

Comment:
22.3 This states a post admission assessment shall be completed, with no time stipulation so would this now be yearly? Or at what interval, also by clinician or physician? If this if by the clinician still feel that this is most appropriate prior to induction versus post to ensure appropriate level of care.
Response:
The Department has reviewed this comment. Existing provisions in the rule address this issue adequately, and, therefore, no changes were made.

Comment:
22.5. As clinically necessary? It is the most necessary component of MAT. People have been getting clean for years and years without medication. Without the counseling and support of groups like AA or NA, you only have someone "not using" and simply treading water. Outcomes will absolutely fall through the floor and "as clinically necessary" makes it sound like it may not be and to delete the portion of the sentence that speaks to the requirements mandated are ONLY minimum guidelines again is contrary to best practices. The Medicaid regs detail best practice and are the minimum.
Response:
The Department has reviewed this comment and finds clarification is needed, therefore, changes were made.

Section 23 Counseling

Comment:
All Counseling should be at the discretion of the treating physician and the treating counselor.
Response:
The Department has reviewed this comment. This comment is general in nature and offers no specific amendment.

Comment:
23.1 If that is not a concise explanation for why counseling is essential, we do not know what is. The medication alone will do nothing except set the person up to fail. ***Please*** leave this line in the rule.
Response:
The Department has reviewed this comment and finds clarification is needed, therefore, changes were made.

Comment:
23.3.1., 23.3.2., 23.3.3. As needed or indicated by whom? Really want to minimize/negate the need for the "AT" in MAT? Medicaid regs still apply to anyone with a medical card.
Response:
The Department has reviewed this comment and finds clarification is needed, therefore, changes were made.

Comment:
Removed section 25.7. Best practice and experience shows us that when someone relapses, minimizing it is the worst thing we can do for the patient. The very lives depend on addressing the issues that drive the relapse. Otherwise the patient may go into a cycle of relapse that it difficult to impossible to break.
Response:
The Department has reviewed this comment, and no changes were made. Registered providers may create a policy to address the issue.

Section 24 Post-Admission Assessment

Comment:
Regulation regarding frequently checking medical labs aside from HIV and hepatitis C are unnecessary and are contributing to the financial burden on the healthcare system.
Response:
The Department has reviewed this comment. Existing provisions in the rule address this issue adequately, and, therefore, no changes were made.

Section 25 Individualized Plan of Care or Treatment Services

Comment:
Treatment Plans should be reviewed and updated every six months.
Response:
The Department has reviewed this comment. Existing provisions in the rule address this issue adequately, and, therefore, no changes were made.

Comment:
25.3 – Is there a uniform way across all agencies that we are to document that the physician has reviewed the tx strategies?
Response:
The Department has reviewed this comment, and no changes were made. Registered providers may create a policy to address the issue.

Comment:
25.3 Is there a uniform way across all agencies that we are to document that the physician has reviewed the tx strategies?
Response:
The Department has reviewed this comment, and no changes were made. Registered providers may create a policy to address the issue.

Comment:
25.7.3.g. Can't be estimated for the vast majority of patients. This calls for a "guestimate". Recovery is a life-time process.
Response:
The Department has reviewed this comment and finds clarification is needed, therefore, changes were made.

Section 26 Administrative Withdrawal

Comment:
Part 26 of the rule is in regard to administrative withdrawal, which is defined in this rule along with administrative detoxification as the "the detoxification from the approved medication-assisted treatment medication for the safety and well-being of the patient, other patients, and staff of the OBMAT program." WVSAM and ASAM are very concerned with this provision regardless of the legitimate reasons listed, as forced withdrawal can put the patient at risk of relapse, overdose, and death, thus countering the fundamental need of having them enter treatment. It is also important to mention that anytime patients discontinue treatment, the result is an increase in morbidity and mortality in the state, which, in turn, would increase overall healthcare and criminal justice costs. We understand that administrative withdrawal would be a measure of last resort after the physician has tried to work with the patient to address behaviors that are in their control, which is mentioned under "non-payment of fees" as a reason of requiring administrative withdrawal. To ensure the patient's care and wellbeing is still the primary focus even during administrative withdrawal, WVSAM and ASAM request the second sentence under provision 26.1 to state "administrative withdrawal should be used as a last resort after the OBMAT program exhausts all efforts to address the patient's behavior or actions that would warrant administrative withdrawal."
Response:
The Department has reviewed this comment and finds clarification is needed, therefore, changes were made.

Comment:
Remove 26.5. Obtaining a negative pregnancy screen on all female patients administratively withdrawn from the program is not possible. Some patients are withdrawn for not presenting to the program. Some are withdrawn for not complying with the rules of the program and are unwilling to consent for a pregnancy screen.
Response:
The Department has reviewed this comment and finds clarification is needed, therefore, changes were made.

Section 28 Laboratory Services; Drug Screens

Comment:
Drug Testing that is sent to a lab for confirmation should be limited to one test every thirty days.
Response:
The Department has reviewed these comments. This comment is general in nature and offers no specific amendment.

Comment:
Addend 28.1 and 28.2.4a. Remove the monthly requirement for drug testing for patients who have demonstrated long-term stability. For example, a patient who has been compliant with treatment for three years and engaged in normal, busy life activities. Now healthy, she is consumed with work and family responsibilities and lives far away from her treatment provider. Having her present monthly is an undue burden. The frequency of screens for these long-term patients with demonstrated stability should be at the discretion of the provider.
Response:
The Department has reviewed this comment and finds clarification is needed, therefore, changes were made.

Comment:
Addend 28.2.2 to state "…have the capability of obtaining medication and or metabolite levels through biologic screening when clinically indicated or through random testing." Blood levels are not necessary as these can be obtained in urine.
Response:
The Department has reviewed this comment, and no changes were made. Registered providers may create a policy to address the issue.

Comment:
Addend 28.2.9 to strike out "opiates" and finish the sentence as "…elimination of substances."
Response:
The Department has reviewed this comment and finds clarification is needed, therefore, changes were made.

Former Section 28 Detoxification Program

Comment:
69.12.28 – Want to clarify that programs can offer all short term, long term and maintenance, whatever is most appropriate for the clients care. This appears to be removing short and long term detox as an option.
Response:
The Department has reviewed this comment, and no changes were made. Registered providers may create a policy to address the issue.

Comment:
69.12.28 Want to clarify that programs can offer all short term, long term and maintenance, whatever is most appropriate for the clients care. This appears to be removing short and long term detox as an option.
Response:
The Department has reviewed this comment, and no changes were made. Registered providers may create a policy to address the issue.

Section 29 Special Populations

Comment:
We suggest revising the language in subsection 29.5.3 on "opioid-addicted pregnant women" to person first language, such as pregnant women with OUD.
Response:
The Department has reviewed this comment and finds clarification is needed, therefore, changes were made.

Comment:
Remove the stigmatizing language of "opioid-addicted pregnant women" in 29.5.3 and replace with "pregnant women with active opioid use disorder."
Response:
The Department has reviewed this comment and finds clarification is needed, therefore, changes were made.

Comment:
29.5.5. We suggest imploring providers to discharge pregnant woman as a last resort and mandate that when she is referred to another service provider, transfer of care is verified.
Response:
The Department has reviewed this comment and finds clarification is needed, therefore, changes were made.

Comment:
As above, in 29.5.5. a referral is not always possible in an administrative discharge as the patient may be lost to follow up or refuse the referral.
Response:
The Department has reviewed this comment and finds clarification is needed, therefore, changes were made.

Section 31 Penalties and Equitable Relief

Comment:
In addition, we believe the fines listed under Part 31 detailing penalties and equitable relief could force OBMAT programs to close indefinitely when the infraction could be resolved in an amenable manner to allow them to continue operating. We ask these fines to also be lowered and those that are applies "per day" should instead only be applied at one time.
Response:
The Department has reviewed this comment, and no change were made in response. The rule provision is consistent with the requirements of the statute.

Lawson, Kathy M

From: Sullivan, Nancy J
Sent: Monday, July 23, 2018 9:44 AM
To: Lawson, Kathy M
Subject: FW: 69 CSR 12

In case I did not share this on Friday.

Nancy J. Sullivan, MAJ
Acting Commissioner, Bureau for Behavioral Health and Health Facilities, and
Assistant to the Cabinet Secretary
West Virginia Department of Health and Human Resources
One Davis Square
Suite 100, East
Charleston, WV 25301
(304) 558-9998

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From: Birckhead, Elliot H
Sent: Friday, July 20, 2018 5:22 PM
To: Sullivan, Nancy J <Nancy.J.Sullivan@wv.gov>
Cc: Matney, James A <James.A.Matney@wv.gov>; Morrison, Beth J <Beth.J.Morrison@wv.gov>; Roth, Rebecca E <Rebecca.E.Roth@wv.gov>; Tennis, Nikki A <Nikki.A.Tennis@wv.gov>
Subject: FW: 69 CSR 12

Nancy – Once again the IG's Office has been very responsive to the issues we raised earlier and these are our only remaining comments on the OBMAT rule, 69 CSR 12:

We are most appreciative of the addition of the Chapter 16-5Y-2 code definitions that were included as an addendum to the rule.

Subsection 8.2.1 creates a process allowing for cash payments to OBMATs when they are document in the patient's record. While we support a flexible approach for people who don't have Medicaid and/or are underinsured or uninsured, Jim Matney tells me that he is getting reports of a number of seedy-looking/ less than reputable cash only OBMATs popping up around the state, allegedly with lines of people hanging outside the building. While this sounds more like an OTP dispensing methadone rather than an OBMAT doc writing prescriptions out of an office, some fairly knowledgeable folks are relying these concerns to us and we're not totally clear on what mechanisms are available when these likely unregistered fly by night programs pop up. While we recognize that this is a delicate balance, these operators do detract from legitimate providers so it might be helpful to set up some specific publicly posted complaint mechanism for people to use to report such alleged programs to the IG's office when they see one.

Subsection 19.3 creates a rebuttable presumption that patients must be 18 + to access MAT but we are aware of model programs in Ohio and elsewhere serving older adolescents 16 + and buprenorphine is approved for people in that age

range. Unfortunately, adolescents, like everyone else in WV, are potentially vulnerable to OUD and we suggest allowing unemancipated minors access to MAT as long as it is clinically indicated with parental consent.

There is no punctuation at the end of new section 24.3 after the word "objectives" on pg. 41.

We suggest revising the language in subsection 29.5.3 on "opioid-addicted pregnant women" to person first language, such as pregnant women with OUD.

Elliott

From: Lawson, Kathy M
Sent: Thursday, June 21, 2018 5:21 PM
To: Lawson, Kathy M <Kathy.M.Lawson@wv.gov>
Cc: Lee, Sheila R <Sheila.R.Lee@wv.gov>; Garlow, Richelle K <Richelle.K.Garlow@wv.gov>; Marra, Jolynn <Jolynn.Marra@wv.gov>; Whitmore, Jessica Y <Jessica.Y.Whitmore@wv.gov>
Subject: 69 CSR 12

Good evening.

The Office-Based Medication-Assisted Treatment rule has been filed with the Secretary of State and is open for public comment until July 21, 2018. A link to the filed rule is provided below for your convenience.

Thank you for your participation and input into the rulemaking process, and we look forward to receiving and reviewing any written public comments you may have.

http://apps.sos.wv.gov/adlaw/csr/ruleview.aspx?document=16884&KeyWord=

Kathy Lawson
Inspector General
WV Department of Health and Human Resources
Building 6, Room 817
State Capitol Complex
Charleston, West Virginia 25305

Tel: 304-558-2278
Fax: 304-558-1992
Email: kathy.m.lawson@wv.gov

Lawson, Kathy M

From: Matthew Christiansen <mattchristiansen@gmail.com>
Sent: Wednesday, June 27, 2018 9:46 AM
To: Lawson, Kathy M
Subject: Fwd: FW: 69 CSR 12

Kathy,
I clicked the link but couldn't find a field to comment. My comments are attached below and I haven't heard anything back from my previous emails so wanted to make sure they were logged in the comment section. Thank you,
Matthew Christiansen MD MPH

-----Original Message-----
From: Christiansen, Matthew Q.
Sent: Wednesday, June 13, 2018 3:20 PM
To: bill.j.crouch@wv.gov
Cc: Becker, James <becker1@marshall.edu>
Subject: FW: FW: DRAFT OBMAT Rule

Bill,
This email was forwarded to me, if you could please forward my comments on to those addressing the rule changes. I sent out a similar set of concerns last year, but didn't get any feedback at the time.

There needs to be an outlet for primary care physicians to treat opioid addiction in the context of their own practices through MAT. The way the current OBMAT rules are written, it is incentived to build high volume, addiction-specific specialty practices. This is a barrier in and of itself to getting treatment with little evidence that it improve outcomes. It also contributes to the stigma (ie. methadone clinics) and concentrates people with similar disease/lifestyle issues. We don't isolate people with heart failure or diabetes or hypertension out of primary care and into sub-specialty clinics just because one is harder to manage than another, and we shouldn't do it with addiction medicine either. In primary care we see addiction related disorders every day, and referring out to other providers for treatment fragments care for something that is imminently handled by a PCP. Of course, if the provider isn't interested there is always the option to refer out. I understand there is a strong incentive to make sure that we are doing MAT right and reducing diversion, but I don't know of any evidence that this approach is more effective. I envision a system where a PCP could treat up to 5 or 10 of their own previously established patients with MAT while requiring weekly counseling and/or documented meetings with oversight and reporting requirements to OHFLAC. If there is more interest in this model I would be happy to help draft a concept that would be successful in a primary care practice.
Thank you,
Matthew Christiansen

Matthew Christiansen, MD, MPH
Department of Family and Community Health Marshall University School of Medicine
1600 Medical Center Drive, Suite 1400
Huntington, WV 25701
(304) 691-1767
christiansen@marshall.edu

From: Lawson, Kathy M [mailto:Kathy.M.Lawson@wv.gov]

Sent: Thursday, June 21, 2018 5:21 PM
To: Lawson, Kathy M <Kathy.M.Lawson@wv.gov>
Cc: Lee, Sheila R <Sheila.R.Lee@wv.gov>; Garlow, Richelle K <Richelle.K.Garlow@wv.gov>; Marra, Jolynn <Jolynn.Marra@wv.gov>; Whitmore, Jessica Y <Jessica.Y.Whitmore@wv.gov>
Subject: 69 CSR 12

Good evening.

The Office-Based Medication-Assisted Treatment rule has been filed with the Secretary of State and is open for public comment until July 21, 2018. A link to the filed rule is provided below for your convenience.

Thank you for your participation and input into the rulemaking process, and we look forward to receiving and reviewing any written public comments you may have.

http://apps.sos.wv.gov/adlaw/csr/ruleview.aspx?document=16884&KeyWord=

Kathy Lawson
Inspector General
WV Department of Health and Human Resources
Building 6, Room 817
State Capitol Complex
Charleston, West Virginia 25305

Tel: 304-558-2278
Fax: 304-558-1992
Email: kathy.m.lawson@wv.gov<mailto:kathy.m.lawson@wv.gov>

WestVirginiaUniversity.

July 18, 2018

Kathy Lawson, Inspector General
State Capitol Complex
Building 6, Room 817
Charleston, WV 25305

RE: Public comment for 69CSR12

Dear Inspector General Lawson,

Prior to offering my recommendations regarding the legislative rule, I believe it is important to provide the history, context and purpose of office based buprenorphine treatment.

Prior to the Drug Abuse Treatment Act of 2000, the only opioid agonist medication permitted to treat Opioid Use Disorder (OUD) was methadone. Methadone treatment was (and continues to be) highly regulated by state and federal authorities. An unintended consequence of the regulation was to segregate Substance Use Disorder (SUD) treatment from general medical care as treatment could only occur in designated methadone clinics. This severely limited access to treatment and added to the stigma of SUD. A person suffering from this disease could not access an evidence-based medication in their doctor's office. Please note, it wasn't the medication itself that motivated the regulations, rather it was the disease: Addiction. Doctors were (and still are) allowed to prescribe methadone in their offices for pain, just not for SUD.

As the growing tide of OUD became apparent in the late nineties, health authorities realized physicians needed a tool to manage severe opioid cravings and withdrawal in their own offices. Buprenorphine was selected based on it's unique pharmacologic properties as a partial opioid agonist and a decade's worth of evidence demonstrating safety and efficacy in France. The intent was not to silo SUD treatment any longer but equip physicians to treat SUD as they would any other chronic disease.

The clinician is required to achieve special training requirements and obtain a waiver from the DEA. Like methadone, this was required not because of any inherent danger beyond other controlled substances, rather because it would be used to treat SUD.

The context today is that physicians may prescribe every legal controlled substance as part of their routine medical practice. Physicians undergo four years of medical school as well as several years of medical residency training and life-long continuing education activities in order to be sufficiently equipped to do so. They are regulated by state medical licensing boards to ensure practice meets the standard of care. They are further regulated by the DEA to ensure safety.

As a licensed physician in West Virginia, I can prescribe an unlimited supply of Neurontin, Xanax and Adderall to as many patients who may request them. There are no additional rules required by legislators or state agents requiring such items as referral to vocational training or specifying the arrangements needed to be made when I go on vacation. There is no senate bill mandating an inspection by OHFLAC or extensive reporting requirements. Each one of these medications mentioned

DEPARTMENT OF BEHAVIORAL MEDICINE AND PSYCHIATRY
PO Box 9137 · 930 Chestnut Ridge Rd
Morgantown, WV 26506
304.293.5023 304.293.3724

above is diverted and sold on the street. The difference is these are not used to treat SUD. Once again, the disease is discriminated against. Why further stigmatize those patients who actually are brave enough to admit they have a problem by placing burdens on providers not required for prescribing controlled substances for other conditions?

Buprenorphine is a life saving medication. This is no hyperbole. The fact is well-documented in the scientific literature and borne out in my clinical experience treating patients with the medicine for the past 14 years. Every major medical society and national health agency acknowledges that ready access to MAT is essential for curbing the opioid addiction crisis. These agencies have a unified message: eliminate barriers preventing immediate and ongoing access to responsible buprenorphine prescribers. Accordingly, most states have eased these burdens. West Virginia has the most restrictive legislative requirements codified in state law. This is tragic since West Virginia leads the nation in opioid overdose deaths.

Imagine if the same state rules required for buprenorphine were required for insulin, another life saving medication. Insulin should be properly thought of as medication assisted treatment for type 2 diabetes. For most, dietary counseling and exercise therapy plus medication is optimal to achieve best results. West Virginia has one of the highest rates of diabetes in the country, which may also be legitimately described as an epidemic. It would truly be a tragedy if physicians were in any way hampered from providing this necessary treatment. One sure way to hamper physician engagement would be to legislate down to the finest detail how the treatment must be conducted. Especially if this is not based on scientific evidence or expert consensus. Another certain way to minimize physician engagement would be to add additional application fees, mandate burdensome reporting requirements and subject offices to site examinations.

Because many doctors are liable to the same prejudices regarding SUD as the general population, they are not quick to sign up to treat this disease. The prospect of adding a significant economic and time burden to do so is simply too much for most.

At the same time, the reality of buprenorphine diversion must be acknowledged. Measures should be in place to minimize this diversion and support providers who prescribe responsibly. The challenge is to achieve the proper balance of regulation versus access. I appreciate the Department of Health and Human Resources effort to attempt this balance by recognizing the overly prescriptive nature of the originally drafted rule. I strongly support all the recommended deletions in the current draft. In addition, I recommend the following changes:

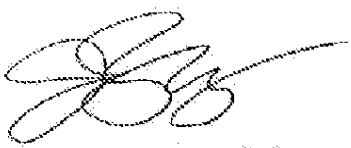
1. Remove the reporting requirements in 13.2 and 13.3. These reporting requirements are unnecessary and overly burdensome. I support keeping records of adverse events and policies on how to deal with these as part of any routine medical practice. I do not believe it is necessary to report these to the state.
2. Remove 19.3 regarding age requirement. Buprenorphine is approved for patients 16 years and older. The strict requirement of an application to the state opioid treatment authority would limit access to adolescents who acutely need this medication in order to reduce overdose risk and engage in treatment.

DEPARTMENT OF BEHAVIORAL MEDICINE AND PSYCHIATRY
PO Box 9137 | 930 Chestnut Ridge Rd
Morgantown, WV 26506
304.293.5533 304.293.6724

3. Remove 20.2. This is not clear on how a program is to "check the records of opioid treatment programs to ensure that the patient is not currently enrolled in those programs as well." Certainly, this would rarely be practicable on a routine basis. There is no current mechanism to do so. The only way a prescriber would know if a patient has been enrolled in another program is if the patient divulges this information or the medication is listed on the controlled substances monitoring program database.
4. Remove 22.1. Providing or referring to vocational and educational services, although of value, is beyond the scope of basic best medical practices and beyond accepted MAT guidelines.
5. Remove 26.5. Obtaining a negative pregnancy screen on all female patients administratively withdrawn from the program is not possible. Some patients are withdrawn for not presenting to the program. Some are withdrawn for not complying with the rules of the program and are unwilling to consent for a pregnancy screen.
6. Addend 28.1 and 28.2.4a. Remove the monthly requirement for drug testing for patients who have demonstrated long-term stability. For example, a patient who has been compliant with treatment for three years and engaged in normal, busy life activities. Now healthy, she is consumed with work and family responsibilities and lives far away from her treatment provider. Having her present monthly is an undue burden. The frequency of screens for these long-term patients with demonstrated stability should be at the discretion of the provider.
7. Addend 28.2.2 to state "...have the capability of obtaining medication and or metabolite levels through biologic screening when clinically indicated or through random testing." Blood levels are not necessary as these can be obtained in urine.
8. Addend 28.2.9 to strike out "opiates" and finish the sentence as "...elimination of substances."
9. Remove the stigmatizing language of "opioid-addicted pregnant women" in 29.5.3 and replace with "pregnant women with active opioid use disorder."
10. As above, in 29.5.5, a referral is not always possible in an administrative discharge as the patient may be lost to follow up or refuse the referral.

I also am greatly encouraged by the removal of clinicians treating thirty patients or less from this rule. Furthermore, I recommend an exemption be considered for those who are part of a state-recognized consortium of responsible MAT providers. As treatment demand continues to expand, so does the need to increase immediate access. An approved consortium may be created to provide formal, ongoing MAT-mentorship for clinicians in our communities who want to treat more than thirty patients, but are hindered by the current regulatory burden.

Sincerely,



James H. Berry D.O.

Associate Professor and Vice Chair
Director of Addictions

DEPARTMENT OF BEHAVIORAL MEDICINE AND PSYCHIATRY

PO Box 9187 | 880 Chestnut Ridge Rd
Morgantown, WV 26506
304.293.5523 304.293.8724

Lawson, Kathy M

From: saad zafar <saadzafardo@gmail.com>
Sent: Friday, July 20, 2018 11:30 PM
To: Lawson, Kathy M
Subject: MAT
Attachments: 69CSR12.pdf

I am writing in support of the letter written by Dr Berry attached to this email. Additional comments that would add to a letter are stated below.

1. Regulations regarding who can provide group therapy for patient are suffering from addiction needs to be readdressed and more people with counseling experiencing should be allowed to provide this service given that current regulations place a huge burden on providers and there is a shortage of providers for MAT let alone therapy.

2. Regulation regarding frequently checking medical labs aside from HIV and hepatitis C are unnecessary and are contributing to the financial burden on the healthcare system.

3. Regulations regarding checking board of pharmacy each visit which could be weekly needs to be readdressed to change to monthly, given that board of pharmacy is not updated quick enough from the time patient fills the medication and sees a provider for the following visit.

As a provider in private practice currently treating patients with addiction, I believe we need to increase access to structured based MAT programs. Increasing access to treatment will also help address this stigma which is associated with seeking treatment for a disease.

--

Saad Zafar, D.O.
Internal Medicine

Farhat Medical Clinic

Physical Address:
330 North Eisenhower Drive
Beckley, WV 25801

Mailing Address:
P.O.Box 283
Stanaford, WV 25927

Email:
DoctorSaadZafar@gmail.com
SaadZafarDO@gmail.com
AlWahhabPLLC@gmail.com

Phone:
Office Phone: (304)-250-7611
Office Fax: (855)-652-7320
Business Cell: (304)-786-9036
eFax: (206)-426-8841
Personal Cell: (304)-228-7786

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Comments on OBMAT Title Series 69-12

2.22 Concerns that the initial assessment is still important to be included to ensure that the client wanting to have an induction into the program is in fact appropriate at least preliminarily to be scheduled for an assessment and induction. The only difference is that the initial assessment done by a clinician would not make a dose recommendation as this would be the physician recommendation upon induction process. Also concerned that without this initial assessment the client will not have sufficient time to review the program requirements, ask questions prior to starting on medication and then could end up having compliance issues. By having an initial assessment prior to seeing the physician, the client has an opportunity to thoroughly review the treatment and make a fully informed decision.

8.1.c.2 being removed to provide 24 hour information for health care providers but section 9.3.2 states still must have, (I am assuming by emergency for an MAT client this could also mean a hospital needing to verify dose in any emergency situation)?

13.3.f-appears to be removing requirement for motality report? OHFLAC requires this.

Completion of an orientation for clients has been marked through in some sections, but still stated as required in others. Example: 60.12.23 marked out, 14.4 marked out, but included in 14.3.4 and 17.4-17.5 just need clarification that orientation is still required and strike out was only due to moving it to be included in one area versus multiple. Also "at the earliest opportunity" needs clarification, is this within a week or two weeks, etc. of beginning the program or sooner?

16.5 use of electronic prescribing removed, however, being able to send to the pharmacy electronically is actually a safer way, no chance of the client losing or misplacing a script or of it getting stolen.

Concerns regarding the removal of the 20.5 section as this aids' in ensuring that the appropriate level of care is offered.

Need clarification of 20.2, what would be considered when practicable, the Board of Pharmacy is run on all clients, when would it be deemed practicable to check other OTP programs, what mile radius and home many, does this mean OTP clinics only or does this mean any practitioner on the SAMHSA facility locator in the catchment area?

22.3 This states a post admission assessment shall be completed, with no time stipulation so would this now be yearly? Or at what interval, also by clinician or physician? If this if by the clinician still feel that this is most appropriate prior to induction versus post to ensure appropriate level of care.

25.3-Is there a uniform way across all agencies that we are to document that the physician has reviewed the tx strategies?

69.12.28-Want to clarify that programs can offer all short term, long term and maintenance, whatever is most appropriate for the clients care. This appears to be removing short and long tern detox as an option.

Lawson, Kathy M

From: Frank Hartman <frank@h2cstrategies.com>
Sent: Monday, July 23, 2018 2:27 PM
To: Lawson, Kathy M
Subject: OBMAT rules pursuant to SB 273 (69 CSR 12)

Ms. Lawson:

I am writing on behalf of my client, Indivior, to provide the following comment on the proposed administrative rules under 69 CSR 12 necessitated by the recent passage of SB 273:

69-12-19.3 "The person desiring medication-assisted treatment must be at least 18 years of age. Exceptions may be made by application with parental consent..." While the exception with consent of a parent is helpful, the treatment is approved by the FDA for patients who are at least 16 years of age. Inasmuch as that age range is the scientific standard, we believe this rule should be changed to "at least 16 years of age..." Additionally, requiring the patient be at least 18 years of age effectively denies treatment of individuals currently housed in the juvenile correctional system and who may benefit greatly from the availability of medication-assisted treatment. For those reasons we request the rule be changed to include patients who are at least 16 years of age.

Thank you for your kind attention to this matter.

Sincerely,

Frank Hartman
H2C Public Policy Strategists, LLC

Connect with H2C:
www.h2cstrategies.com | @H2Cstrategies | H2C on Facebook

Call H2C from this email: 800-346-5127

Lawson, Kathy M

From: Honaker, Kimberly <Kimberly.Honaker@hsc.wvu.edu>
Sent: Friday, July 20, 2018 9:42 AM
To: Lawson, Kathy M
Subject: RE: Public comment for 69CSR12

July 19th, 2018
Kathy Lawson,
Inspector General
State Capitol
Complex
Building 6, Room 817
Charleston, WV 25305

RE: Public comment for 69CSR12

Dear Inspector General Lawson,

I began my career working in the Addiction's Field in 1991. At that time cocaine, then crack cocaine, was rampant in our population.

In 2002, I began working with a physician in Greene County, Pennsylvania, on a grant that was the first to utilize buprenorphine as a treatment for opioid addiction in Southwestern Pennsylvania.

I was very skeptical of this new medication, I talked to the physician and asked: "How can you treat addiction with a drug for a drug?" – a question many people continue to ask. But what I saw was: it worked.

In 2006, I began working in West Virginia on a clinical trial that utilized buprenorphine. I watched people in our clinic who were prescribed buprenorphine, engage in a robust recovery regimen that included therapy, meeting weekly with physicians trained in addiction treatment utilizing buprenorphine, and required recovery community engagement. That is when I really saw, in large numbers, how this medication could save lives, and even more remarkable: enable people to lead successful family and working lives, becoming vital, contributing members to their communities. Our research trial looked at recovery success rates during and after a taper period. It was dismal. The rates of people staying off opioids without buprenorphine were frightening

The backlash that has happened in the 12 step recovery communities and the Addictions' treatment professional communities, saddens me greatly. It is shocking to witness the bullying by other educated professionals & other recovering addicts, urging people to: "get off that medication." I have watched many people die, returning to opioid use, after discontinuing treatment with buprenorphine. We do need safeguards in place,

and physicians need to be educated in the appropriate use of buprenorphine and treatment of people with opioid use disorder.

Our young people are dying, grandparents, great-grandparents are raising infants and toddlers, with little help. All of us: my family, my colleagues, physicians, therapists, other researchers, community members, guardians of our State -like you- who serve in our Government, struggle in the face of this devastating epidemic.

I have spent my entire adult life working in the addictions field in one aspect or another. Buprenorphine is the only medication I have seen that has had remarkable life-saving, long standing results, for opioid addicts.

As a citizen of our Great Nation and my beloved West Virginia, I sincerely urge you to consider eliminating these barriers that prevent responsible buprenorphine prescribers from helping save lives in West Virginia.

1. Remove the reporting requirements in 13.2 and 13.3. These reporting requirements are unnecessary and overly burdensome. I support keeping records of adverse events and policies on how to deal with these as part of any routine medical practice. I do not believe it is necessary to report these to the state.
2. Remove 19.3 regarding age requirement. Buprenorphine is approved for patients 16 years and older. The strict requirement of an application to the state opioid treatment authority would limit access to adolescents who acutely need this medication in order to reduce overdose risk and engage in treatment.

Thank you very much for your service to West Virginia & for hearing my concerns,

Kimberly

Kimberly D. Honaker, B.A.
Research Coordinator/Grants Administrator
WVU School of Medicine
Department of Behavioral Medicine & Psychiatry
Kimberly.Honaker@hsc.wvu.edu
304-293-9191

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PROVIDER BASED FACILITY OF CABELL HUNTINGTON HOSPITAL INC.
1115 20th Street, Suite 200
Huntington, WV 25703
304-691-1500
FAX: 304-523-4358

July 20, 2018

Kathy Lawson, Inspector General
State Capitol Complex
Building 6, Room 817
Charleston, WV 25305

RE: Public comment for 69CSR12

Dear Inspector General Lawson,

I am a clinical and forensic psychologist practicing in Huntington, WV in Cabell County, which in recent past has held the dubious distinction as the overdose capitol of the state. I am the sole therapist for the Recovery Center, an outpatient MAT clinic serving, at present, 30 individuals in recovery and the MARC program, a MAT clinic for pregnant and early postpartum mothers, serving an additional 30-36 women. I joined the treatment team at Recovery Center last year, around the time the program was restructuring to comply with the new OBMAT guidelines. We were at one point serving over 100 patients with responsible prescribing practices. We have lost many patients over the past year to clinics that do not participate in OBMAT. Staff at Recovery Center have often commented to one another about how difficult it would be for any of us to keep up with the requirements if we were in our patients' positions.

While I am in favor of state oversight of MAT programs, and have seen from my own professional experience that patients in structured programs tend to do well in their recovery, I am aware that some of the guidelines are unduly burdensome for patients and prescribers alike. We have absorbed patients from multiple private practitioners who quit prescribing buprenorphine because they were unwilling or unable to comply with OBMAT guidelines. These were patients who were stable with medication. Those who have stayed with our clinic despite changes have continued to do well; most have turned to cash clinics, and a minority have relapsed.

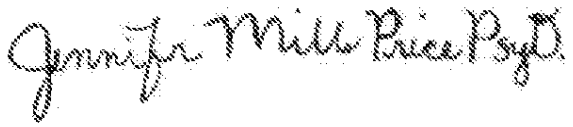
Because I am not a prescriber myself, some of the nuances on the guidelines are lost on me. The following recommendations were brought to my attention by Dr. Jim Berry of WVU, whose program has been providing Recovery Center with guidance in implementing the Comprehensive Opioid Addiction Treatment, or COAT model, and disseminating the model to clinics throughout Southern West Virginia. I am including Dr. Berry's recommendations here, without comment:

1. Remove the reporting requirements in 13.2 and 13.3. These reporting requirements are unnecessary and overly burdensome. I support keeping records of adverse events and policies on how to deal with these as part of any routine medical practice. I do not believe it is necessary to report these to the state.
2. Remove 19.3 regarding age requirement. Buprenorphine is approved for patients 16 years and older. The strict requirement of an application to the state opioid treatment authority would limit access to adolescents who acutely need this medication in order to reduce overdose risk and engage in treatment.

3. Remove 20.2. This is not clear on how a program is to "check the records of opioid treatment programs to ensure that the patient is not currently enrolled in those programs as well." Certainly, this would rarely be practicable on a routine basis. There is no current mechanism to do so. The only way a prescriber would know if a patient has been enrolled in another program is if the patient divulges this information or the medication is listed on the controlled substances monitoring program database.
4. Remove 22.1. Providing or referring to vocational and educational services, although of value, is beyond the scope of basic best medical practices and beyond accepted MAT guidelines.
5. Remove 26.5. Obtaining a negative pregnancy screen on all female patients administratively withdrawn from the program is not possible. Some patients are withdrawn for not presenting to the program. Some are withdrawn for not complying with the rules of the program and are unwilling to consent for a pregnancy screen.
6. Addend 28.1 and 28.2.4a. Remove the monthly requirement for drug testing for patients who have demonstrated long-term stability. For example, a patient who has been compliant with treatment for three years and engaged in normal, busy life activities. Now healthy, she is consumed with work and family responsibilities and lives far away from her treatment provider. Having her present monthly is an undue burden. The frequency of screens for these long-term patients with demonstrated stability should be at the discretion of the provider.
7. Addend 28.2.2 to state "...have the capability of obtaining medication and or metabolite levels through biologic screening when clinically indicated or through random testing." Blood levels are not necessary as these can be obtained in urine.
8. Addend 28.2.9 to strike out "opiates" and finish the sentence as "...elimination of substances."
9. Remove the stigmatizing language of "opioid-addicted pregnant women" in 29.5.3 and replace with "pregnant women with active opioid use disorder."
10. As above, in 29.5.5. a referral is not always possible in an administrative discharge as the patient may be lost to follow up or refuse the referral.

It is an honor and a privilege to walk alongside people in their journey from active addiction to recovery. Buprenorphine, though not a long-term solution to opioid dependence in and of itself, stabilizes very sick people relatively quickly, and allows them to participate actively in treatment. However, treatment that becomes burdensome to patients can prevent them from participating actively in their lives.

Sincerely,



Jennifer Mills Price, Psy.D.
Assistant Professor, Marshall University Joan C. Edwards School of Medicine
Department of Psychiatry and Behavioral Medicine
Licensed Psychologist WV #1064

STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
OFFICE OF THE INSPECTOR GENERAL

MEDICAID FRAUD CONTROL UNIT

408 Leon Sullivan Way
Charleston, West Virginia 25301
Telephone: (304) 558-1858 Fax: (304) 558-3498

Bill Crouch
Cabinet Secretary

Kathy M. Lawson
Inspector General

Comment on 69 CSR 12-8

Date: July 22, 2018

To: Inspector General Kathy Lawson, Esq

CC: Richelle Garlow, Esq., General Counsel

From: Michael Malone, Esq. Deputy Director,

OBMATs have a variety of rules governing both payment methods and treatment methods. Given the general rule that Medicaid is the payor of last resort all allegations of payment in addition to Medicaid are closely scrutinized to protect the integrity of the program and the recipients receiving the care. The OBMAT Statute specifically addresses payment for Medicaid in stating:

> 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:**

W.Va. Code 16-5Y-5(e)(2017)(Emphasis Added) It is also worth noting due to Substance Abuse Treatment issues patients are able to specifically waive such claims being sent to their insurers in that they may waive and pay cash so long the waiver IS "voluntar[y] and with full knowledge of the financial obligations, including all treatment costs, requested a claim not be submitted to their insurer, Medicare, or West Virginia Medicaid." 69 CSR 12 – 8.2 These Statutes would make the OBMAT either decide to submit claims or take cash upon waiver

from the patient. The OBMAT is allowed to either offer their own counseling or supervise patients on a referral basis. See

> **Each medication-assisted treatment program shall designate counseling staff,** either employee or **those used on a referral-basis by the program**, which meet the requirements of this article and the rules promulgated pursuant to this article.

W.Va. Code 16-5Y-5(d)(2017)(Emphasis Added). This allows the OBMAT to submit claims to WV Medicaid and designate(mandate) the use of counseling staff of a non-enrolled but affiliated provider resulting in counseling services which are on a cash only basis. This structure creates the hybrid of Medicaid claims and cash for counseling services. There are a variety of laws that prohibit self-dealing and or kickbacks in healthcare. See Gen. 42 U.S.C. 1395nn or WV Code § 9-7-5(a). The proposed rule currently reads:

> The OBMAT Program shall assign or make a referral to a primary counselor or counseling service for each patient to contribute to the appropriate treatment plan for the patient and to monitor patient progress

69 CSR 12-8 7.5.2. The Medicaid Fraud Control Unit, hereafter MFCU, specifically recommends adding language prohibiting a provider from forcing a patient into an affiliated counseling service where the program and or person in the program has a financial interest unless the program is designating its own counseling staff. The MFCU recommends this to specifically prohibit persons and or corporations from self-dealing while tending to patients seeking rehabilitation from their opioid addictions.[1]

[1] The MFCU is not currently or specifically discussing whether past, current, or future self dealing is legal or illegal under current law and regulations. Solely providing a recommendation that allows for clarity and protection of the citizens of West Virginia.

Lawson, Kathy M

From: Brian Mosley <brianmosleymalpc@gmail.com>
Sent: Wednesday, July 18, 2018 11:34 PM
To: Lawson, Kathy M
Subject: Public comments on proposed changes to MAT Law

Follow Up Flag: Follow up
Flag Status: Completed

Kathy Lawson, WV Inspector General Office

I strongly support the changes to the bill that allow more autonomy for the treating physician , with some points that I will go over, the comments of the behavioral health center executives who were present seem to always place ALL of us in private practice into a negative light, I understand their regulatory burden as I once worked in that area, but with that being said , my interaction with patients who have been in treatment or attempted to enter treatment with a Behavioral Health Center in West Virginia, the following themes seem to be present:
Long waiting lists of up to several months
Expensive and frequent Lab testing (when a good , inexpensive , observed instant test would be permissible).
Unlicensed, ineffectual Counselors providing therapy, people with business degrees, teaching degrees providing therapy.
Multiple visits per week that make it impossible to remain employed , in my informal research not one centers I called offers alternative hours to the 9 to 3 workday they utilize. If a patient is working that is the cornerstone of successful recovery, several patients tell me the behavioral health centers and FQHC's tell them that they can't be employed and be in their treatment program, the bottom line is the centers have the Medicaid patients return frequently so the can bill the state more frequently. The Behavioral Health Centers, FQHC's and other Medicaid centric clinics are engaged in providing treatment in this manner, they need to be looked a.

Drug screens, these are being abused for profit in all Clinic settings, patients are getting stuck with bills for tests their insurance companies refuse to pay for, some clinics have close associations with laboratories , testing limits need to be set, Medicaid is being charged way too much and way too often

Contents of the bill:
Drug Testing that is sent to a lab for confirmation should be limited one test every thirty days.

All Counseling should be at the discretion of the treating physician and the treating counselor.

Counselors should be independently licensed , many offices and centers are utilizing unlicensed Counselors.

Treatment Plans should be reviewed and updated every six months.

We should continue to track patients who expire while in treatment.

I look forward to assisting in the process, thank you for including us in the process.

Brian Mosley MA , LPC, LSW, SAP, ALPS
304-369-3497

Sent from my iPad

Lawson, Kathy M

From: Andrew Dornbos <andrew.dornbos@newlifeclinics.com>
Sent: Monday, July 23, 2018 9:34 AM
To: Lawson, Kathy M
Subject: Comments to 69 CSR 12

Kathy –
I wanted to reiterate the prior comments that I sent you regarding my suggested change to the OBMAT regulation.

Unless I am missing something the regulation makes things easier for cash practices to operate than what the statute provides. Instead of requiring a provider to get a denial from insurance, etc. a provider is able to simply have the patient sign a waiver, which opens the process up for abuses and they operate, essentially, like pill mills at that point. The relevant language is as follows:

W.Va. Code 16-5Y-5(e) provides as follows:

"(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."

69 CSR 12 – 8.2.a goes beyond this and adds the phrase "has voluntarily and with full knowledge of the financial obligations, including all treatment costs, requested a claim not be submitted to their insurer, Medicare, or West Virginia Medicaid."

To my knowledge this additional language is not required by code and based on what I have researched was included in the initial proposed language for the Rule submitted to the SOS on 8/26/2016.

I would request that this language in 8.2.a be removed to simply mirror the requirements of the statute. I do not have any further comments at this time.

Thanks
Andrew

Andrew S. Dornbos
General Counsel
New Life Clinics

The information contained in this transmission may contain privileged and confidential information, including patient information protected by federal and state privacy laws. It is intended only for the use of the person(s) named above. If you are not the intended recipient, you are hereby notified that any review, dissemination, distribution, or duplication of this communication is strictly prohibited. If you are not the intended recipient, please contact the sender by reply email and destroy all copies of the original message.

From: "Lawson, Kathy M" <Kathy.M.Lawson@wv.gov>
Date: Thursday, June 21, 2018 at 5:20 PM
To: "Lawson, Kathy M" <Kathy.M.Lawson@wv.gov>
Cc: "Lee, Sheila R" <Sheila.R.Lee@wv.gov>, "Garlow, Richelle K" <Richelle.K.Garlow@wv.gov>, "Marra, Jolynn" <Jolynn.Marra@wv.gov>, "Whitmore, Jessica Y" <Jessica.Y.Whitmore@wv.gov>
Subject: 69 CSR 12

Good evening.

The Office-Based Medication-Assisted Treatment rule has been filed with the Secretary of State and is open for public comment until July 21, 2018. A link to the filed rule is provided below for your convenience.

Thank you for your participation and input into the rulemaking process, and we look forward to receiving and reviewing any written public comments you may have.

http://apps.sos.wv.gov/adlaw/csr/ruleview.aspx?document=16884&KeyWord=

Kathy Lawson
Inspector General
WV Department of Health and Human Resources
Building 6, Room 817
State Capitol Complex
Charleston, West Virginia 25305

Tel: 304-558-2278
Fax: 304-558-1992
Email: kathy.m.lawson@wv.gov

907 KAR 15:045. Reimbursement provisions and requirements for targeted case management services for individuals with a substance use disorder.

RELATES TO: KRS 205.520, 42 U.S.C. 1396a(a)(10)(B), 42 U.S.C. 1396a(a)(23)
STATUTORY AUTHORITY: KRS 194A.030(2), 194A.050(1), 205.520(3)
NECESSITY, FUNCTION, AND CONFORMITY: The Cabinet for Health and Family Services, Department for Medicaid Services, has a responsibility to administer the Medicaid Program. KRS 205.520(3) authorizes the cabinet, by administrative regulation, to comply with any requirement that may be imposed or opportunity presented by federal law to qualify for federal Medicaid funds. This administrative regulation establishes the reimbursement provisions and requirements regarding Medicaid Program targeted case management services for individuals with a substance use disorder who are not enrolled with a managed care organization.

Section 1. General Requirements. For the department to reimburse for a service covered under this administrative regulation, the service shall be:
(1) Medically necessary;
(2) Provided:
(a) To a recipient;
(b) By a provider that meets the provider participation requirements established in 907 KAR 15:040; and
(c) In accordance with the requirements established in 907 KAR 15:040; and
(3) Covered in accordance with 907 KAR 15:040.

Section 2. Reimbursement. (1) The department shall reimburse a monthly rate of $334 in total for all targeted case management services provided to a recipient during the month.
(2) Except as established in subsection (3) or (4) of this section, to qualify for the reimbursement referenced in subsection (1) of this section, a targeted case management services provider shall provide services to a recipient consisting of at least four (4) targeted case management service contacts including:
(a) At least two (2) face-to-face contacts with the recipient; and
(b) At least two (2) additional contacts which shall be:
1.a. By telephone; or
b. Face-to-face; and
2. With the recipient or with another individual or agency on behalf of the recipient.
(3) For a recipient who is under the age of eighteen (18) years, the contacts that a targeted case management services provider shall have shall include at least:
(a)1. One (1) face-to-face contact with the recipient; and
2. One (1) face-to-face contact with the recipient's parent or legal guardian; and
(b) Two (2) additional contacts which shall be:
1.a. By telephone; or
b. Face-to-face; and
2. With the recipient or with another individual or agency on behalf of the recipient.
(4) For a recipient who is at least eighteen (18) years of age but under the age of twenty-one (21) years, the contacts that a targeted case management services provider shall have shall include:
(a)1. At least two (2) face-to-face contacts with the recipient; and
2. At least two (2) additional contacts which shall be:
a.(i) By telephone; or
(ii) Face-to-face; and
b. With the recipient or with another individual or agency on behalf of the recipient; or
(b)1.a. At least one (1) face-to-face contact with the recipient; and
b. One (1) face-to-face contact with the recipient's parent or legal guardian; and
2. At least two (2) additional contacts which shall be:
a.(i) By telephone; or
(ii) Face-to-face; and
b. With the recipient or with another individual or agency on behalf of the recipient.

Section 3. No Duplication of Service. (1) The department shall not reimburse for a service provided to a recipient by more than one (1) provider of any program in which the same service is covered during the same time period.
(2) For example, if a recipient is receiving targeted case management services from an independent behavioral health provider, the department shall not reimburse for the targeted case management services provided to the same recipient during the same time period by a behavioral health services organization.

Section 4. Not Applicable to Managed Care Organizations. A managed care organization shall not be required to reimburse in accordance with this administrative regulation for a service covered pursuant to:
(1) 907 KAR 15:040; and
(2) This administrative regulation.

Section 5. Federal Approval and Federal Financial Participation. The department's reimbursement for services pursuant to this administrative regulation shall be contingent upon:
(1) Receipt of federal financial participation for the reimbursement; and
(2) Centers for Medicare and Medicaid Services' approval for the reimbursement. (41 Ky.R. 1268; Am. 1818; eff. 4-3-2015.)

907 KAR 15:040. Coverage provisions and requirements regarding targeted case management for individuals with a substance use disorder.

RELATES TO: KRS 205.520, 42 U.S.C. 1396a(a)(10)(B), 42 U.S.C. 1396a(a)(23)
STATUTORY AUTHORITY: KRS 194A.030(2), 194A.050(1), 205.520(3), 42 U.S.C. 1396n(g).
NECESSITY, FUNCTION, AND CONFORMITY: The Cabinet for Health and Family Services, Department for Medicaid Services, has a responsibility to administer the Medicaid Program. KRS 205.520(3) authorizes the cabinet, by administrative regulation, to comply with any requirement that may be imposed or opportunity presented by federal law to qualify for federal Medicaid funds. This administrative regulation establishes the coverage provisions and requirements regarding Medicaid Program targeted case management services for individuals with a substance use disorder.

Section 1. General Coverage Requirements. For the department to reimburse for a service covered under this administrative regulation, the service shall be:
(1) Medically necessary; and
(2) Provided:
(a) To a recipient; and
(b) By a provider that meets the provider participation requirements established in Section 3 of this administrative regulation.

Section 2. Eligibility Criteria. (1) To be eligible to receive targeted case management services under this administrative regulation, a recipient shall:
(a) Have a primary moderate or severe substance use disorder diagnosis or co-occurring moderate or severe substance use disorder and mental health diagnoses;
(b) Have:
1. A lack of access to the supports necessary to assist the recipient in the recipient's recovery;
2. A need for assistance with access to housing, vocational, medical, social, educational, or other community services and supports; or
3. Involvement with one (1) or more child welfare or criminal justice agencies but not be an inmate of a public institution; and
(c) Not be:
1. Between the age of twenty-one (21) years and sixty-four (64) years while receiving services in an institution for mental diseases; or
2. An inmate of a public institution.
(2) A moderate or severe substance use disorder shall be a moderate or severe substance use disorder as defined in the current edition of the American Psychiatric Association Diagnostic and Statistical Manual of Mental Disorders™.
(3) A mental health diagnosis shall be a diagnosis of any mental health condition included in the current edition of the American Psychiatric Association Diagnostic and Statistical Manual of Mental Disorders™.

Section 3. Provider Requirements. (1)(a) To be eligible to provide services under this administrative regulation, an individual, entity, or organization shall:
1. Be currently enrolled in the Kentucky Medicaid Program in accordance with 907 KAR 1:672;
2. Except as established in subsection (2) of this section, be currently participating in the Kentucky Medicaid Program in accordance with 907 KAR 1:671;
3. Be:
a. A community mental health center;
b. An individual or provider group authorized to provide behavioral health services pursuant to 907 KAR 15:010;
c. A behavioral health services organization;
d. A Level I psychiatric residential treatment facility only if the recipient is under twenty-one (21) years of age;
e. A Level II psychiatric residential treatment facility only if the recipient is under twenty-one (21) years of age;
f. A chemical dependency treatment center;
g. An outpatient hospital; or
h. A psychiatric hospital; and
4. Have:
a. For each service it provides, the capacity to provide the full range of the service as established in this administrative regulation;
b. Documented experience in serving the population of individuals with behavioral health disorders relevant to the particular services provided;
c. The administrative capacity to ensure quality of services;
d. A financial management system that provides documentation of services and costs;
e. The capacity to document and maintain individual case records;
f. Documented programmatic and administrative experience in providing comprehensive case management services; and
g. Documented referral systems and linkages and referral ability with essential social and health services agencies.
(b) The documentation referenced in paragraph (a)4.b., f., and g. of this subsection shall be subject to audit by:
1. The department;
2. The Department for Behavioral Health, Developmental and Intellectual Disabilities;
3. The Cabinet for Health and Family Services, Office of Inspector General;
4. A managed care organization, if a targeted case manager provider is enrolled in its network;
5. The Centers for Medicare and Medicaid Services;
6. The Kentucky Office of the Auditor of Public Accounts; or
7. The United States Department of Health and Human Services, Office of the Inspector General.
(2) In accordance with 907 KAR 17:015, Section 3(3), a targeted case management services provider which provides a service to an enrollee shall not be required to be currently participating in the fee-for-service Medicaid Program.

(3) A targeted case management services provider shall:

(a) Agree to provide services in compliance with federal and state laws regardless of age, sex, race, creed, religion, national origin, handicap, or disability; and

(b) Comply with the Americans with Disabilities Act (42 U.S.C. 12101 et seq.) and any amendments to the act.

Section 4. Case Manager Requirements. (1) A case manager shall:

(a)1. Have at least a bachelor of arts or science degree in a behavioral science including:

a. Psychology;
b. Sociology;
c. Social work;
d. Family studies;
e. Human services;
f. Counseling;
g. Nursing;
h. Behavioral analysis;
i. Public health;
j. Special education;
k. Gerontology;
l. Recreational therapy;
m. Education;
n. Occupational therapy;
o. Physical therapy;
p. Speech-language pathology;
q. Rehabilitation counseling; or
r. Faith-based education;

2. Be a certified alcohol and drug counselor who has a bachelor of arts or science degree; or

3. As authorized pursuant to subsection (5) of this section, have:

a. Provided targeted case management services to a recipient any time from April 1, 2014 to the effective date of this administrative regulation; or

b. Supervised the provision of targeted case management services to a recipient any time from April 1, 2014 to the effective date of this administrative regulation;

(b) Have successfully completed case management training pursuant to 908 KAR 2:260; and

(c) Successfully complete continuing education requirements pursuant to 908 KAR 2:260.

(2)(a) Supervision by a behavioral health professional who has completed case management training approved by DBHDID shall occur at least twice per month.

(b) At least one (1) of these supervisory contacts shall be on an individual basis and face-to-face.

(3)(a) Except as established in paragraph (b) of this subsection, a case manager shall have at least one (1) year of full-time employment working directly with individuals in a human service setting after completing the requirements established in subsection (1)(a) of this section.

(b) A master's degree in one (1) of the following behavioral science disciplines may be substituted for the one (1) year of experience:

1. Psychology;
2. Sociology;
3. Social work;
4. Family studies;
5. Human services;
6. Counseling;
7. Nursing;
8. Behavioral analysis;
9. Public health;
10. Special education;
11. Gerontology;
12. Recreational therapy;
13. Education;
14. Occupational therapy;
15. Physical therapy;
16. Speech-language pathology;
17. Rehabilitation counseling; or
18. Faith-based education.

(4) A behavioral health professional shall be:

(a) An advanced practice registered nurse;
(b) A licensed clinical social worker;
(c) A licensed marriage and family therapist;
(d) A licensed professional clinical counselor;
(e) A licensed psychological practitioner;
(f) A licensed psychologist;
(g) A licensed professional art therapist;
(h) A physician;
(i) A psychiatrist;
(j) A behavioral health practitioner under supervision;

(k) A registered nurse working under the supervision of a physician or advanced practice registered nurse; or

(l) An individual with a bachelor's degree stated in subsection (1)(a)1. of this section who:

1. Is working under the supervision of a billing supervisor; and

2. Has at least five (5) years of documented full-time experience providing specialized case management services.

(5)(a) In order to be approved, a request for the targeted case manager qualification exemption established in subsection (1)(a)3. of this section shall be:

1. Submitted in writing to the department, or for an enrollee, to the managed care organization in which the enrollee is enrolled, with documentation of the individual's experience in:

a. Providing targeted case management services to a recipient; or

b. Supervising the provision of targeted case management services to a recipient; and

2. Received by the department or managed care organization no later than June 30, 2015.

(b) The department or managed care organization shall not grant any exemption pursuant to subsection (1)(a)3. of this section that it receives after June 30, 2015.

Section 5. Freedom of Choice of Provider. (1) A recipient shall have the freedom to choose from which:

(a) Case manager to receive services within the recipient's geographic area identified in the recipient's care plan; and

(b) Provider of non-targeted case management Medicaid covered services to receive services.

(2) A case manager shall not have the authority to authorize or deny the provision of non-targeted case management Medicaid covered services to a recipient.

(3) A recipient shall not be required to receive targeted case management services as a condition of receiving non-targeted case management Medicaid-covered services.

Section 6. Covered Services. (1) Targeted case management services covered under this administrative regulation shall:

(a) Be services furnished to assist a recipient in gaining access to needed medical, social, educational, or other services; and

(b) Include:

1. A comprehensive assessment and periodic reassessments of the recipient's needs to determine the need for any medical, educational, social, or other services;

2. The development and periodic revision of a specific care plan for the recipient;

3. A referral or related activities to help the recipient obtain needed services;

4. Monitoring or follow-up activities; or

5. Contacts with non-recipients who are directly related to help with identifying the recipient's needs and care for the purpose of:

a. Helping the recipient access services;

b. Identifying supports necessary to enable the recipient to obtain services;

c. Providing a case manager with useful input regarding the recipient's past or current functioning, symptoms, adherence to treatment, or other information relevant to the recipient's behavioral health condition; or

d. Alerting a case manager to a change in the recipient's needs.

(2)(a) An assessment or reassessment shall include:

1. Taking the recipient's history;

2. Identifying the recipient's strengths and needs and completing related documentation; and

3. Gathering information from other sources including family members, medical providers, social workers, or educators, to form a complete assessment of the recipient.

(b) A face-to-face assessment or reassessment shall be completed:

1. At least annually; or

2. More often if needed based on changes in the recipient's condition.

(3) The development and periodic revision of the recipient's care plan shall:

(a) Specify the goals and actions to address the medical, social, educational, or other services needed by the recipient;

(b) Include ensuring the active participation of the recipient and working with the recipient, the recipient's authorized health care decision maker, or others to develop the goals; and

(c) Identify a course of action to respond to the assessed needs of the recipient.

(4) A referral or related activities shall include activities that help link the recipient with medical providers, social providers, educational providers, or other programs and services that are capable of providing needed services to:

(a) Address the identified needs; and

(b) Achieve goals specified in the care plan.

(5)(a) Monitoring and follow-up activities shall:

1. Be activities and contacts that:

a. Are necessary to ensure that the recipient's care plan is implemented;

b. Adequately address the recipient's strengths and needs; and

c. May be with the recipient, the recipient's family members, the recipient's service providers, or other entities or individuals;

2. Be conducted as frequently as necessary; and

3. Include making necessary adjustments in the recipient's care plan and service arrangements with providers.

(b) Monitoring shall:

1. Occur at least once every three (3) months;

2. Be face-to-face; and

3. Determine if:

a. The services are being furnished in accordance with the recipient's care plan;

b. The services in the recipient's care plan are adequate to meet the recipient's needs; and

c. Changes in the needs or status of the recipient are reflected in the care plan.

Section 7. No Duplication of Service. (1) The department shall not pay for targeted case management services which duplicate services provided by another public agency or a private entity.

(2)(a) The department shall not reimburse for a service provided to a recipient by more than one (1) provider of any program in which the same service is covered during the same time period.

(b) For example, if a recipient is receiving targeted case management service from an independent behavioral health provider, the department shall not reimburse for targeted case management services provided to the same recipient during the same time period by a behavioral health services organization.

Section 8. Exclusions and Limits. (1) Targeted case management services shall not include services defined in 42 C.F.R. 440.169 if the activities:

(a) Are an integral and inseparable component of another covered Medicaid service; or

(b) Constitute the direct delivery of underlying medical, educational, social, or other services to which an eligible recipient has been referred, including:

1. Foster care programs;
2. Research gathering and completing documentation required by the foster care program;
3. Assessing adoption placements;
4. Recruiting or interviewing potential foster care parents;
5. Serving legal papers;
6. Home investigations;
7. Providing transportation;
8. Administering foster care subsidies; or
9. Making placement arrangements.

(2) A recipient who is receiving case management services under a 1915(c) home and community based waiver program shall not be eligible to receive targeted case management services under this administrative regulation.

(3) An individual who provides targeted case management to a recipient shall not provide any other Medicaid covered service to the recipient.

(4)(a) Beginning October 1, 2015, except as established in paragraph (c) of this subsection, if an individual provides targeted case management services to a recipient, the maximum number of recipients to whom the individual may provide services at any point in time, whether targeted case management services or other services, shall be twenty-five (25).

(b) As an example of the limit established in paragraph (a) of this subsection, if an individual provides targeted case management services to ten (10) recipients, the individual may provide individual outpatient therapy to no more than fifteen (15) other recipients at the same time.

(c) The limit established in paragraph (a) of this subsection shall not apply to:

1. Mobile crisis services;
2. Crisis intervention services; or
3. Screenings.

Section 9. Records Maintenance, Documentation, Protection, and Security. (1) A targeted case management services provider shall maintain a current case record for each recipient.

(2)(a) A case record shall document each service provided to the recipient including the date of the service and the signature of the individual who provided the service.

(b) The individual who provided the service shall date and sign the case record within forty-eight (48) hours from the date that the individual provided the service.

(3) A case record shall:

(a) Include:

1. The recipient's name;
2. The time and date corresponding to each occasion in which a service was provided to the recipient;
3. The name of the targeted case management services:
a. Provider agency, if an agency; and
b. Practitioner who provided the targeted case management services;
4. The nature, content, and contacts that occurred regarding the targeted case management services provided;
5. Whether or not goals in the recipient's care plan have been achieved;
6. Whether the recipient has declined to receive any services in the recipient's care plan;
7. A timeline for obtaining needed services; and
8. A timeline for reevaluating the recipient's care plan; and

(b) Be:

1. Maintained in an organized and secure central file;
2. Furnished upon request:
a. To the Cabinet for Health and Family Services; or
b. For an enrollee, to the managed care organization in which the recipient is enrolled or has been enrolled in the past if applicable;
3. Made available for inspection and copying by:
a. Cabinet for Health and Family Services' personnel; or
b. Personnel of the managed care organization in which the recipient is enrolled if applicable;
4. Readily accessible; and
5. Adequate for the purpose of establishing the current treatment modality and progress of the recipient.

(4)(a) A discharge summary shall:

1. Be required, at the time a decision is made that services are terminated, for each recipient who received at least three (3) service visits; and
2. Contain a summary of the significant findings and events during the course of treatment including the:
a. Final assessment regarding the progress of the recipient toward reaching goals and objectives established in the recipient's care plan; and

b. Recipient's condition upon termination and disposition.

(b) A case record relating to a recipient who was terminated from receiving services shall be fully completed within ten (10) business days following termination.

(5) If a recipient's case is reopened within ninety (90) calendar days of terminating services for the same or related issue, a reference to the prior case history with a note regarding the interval period shall be acceptable.

(6) If a recipient is transferred or referred to a health care facility or other provider for care or treatment, the transferring targeted case management services provider shall, within ten (10) business days of awareness of the transfer or referral, transfer the recipient's records in a manner that complies with the records' use and disclosure requirements as established in or required by:

(a) The Health Insurance Portability and Accountability Act codified as 45 C.F.R. Parts 160, 162, and 164;

(b) 42 U.S.C. 1320d-2 to 1320d-8; and

(c) 42 C.F.R. Part 2.

(7)(a) If a targeted case management services provider's Medicaid Program participation status changes as a result of voluntarily terminating from the Medicaid Program, involuntarily terminating from the Medicaid Program, a licensure suspension, or death of an owner or deaths of owners, the case records of the targeted case management services provider shall:

1. Remain the property of the targeted case management services provider; and

2. Be subject to the retention requirements established in subsection (8) of this section.

(b) A targeted case management services provider shall have a written plan addressing how to maintain case records in the event of an owner's death or owners' deaths.

(8)(a) Except as established in paragraph (b) or (c) of this subsection, a targeted case management services provider shall maintain a case record regarding a recipient for at least six (6) years from the last date of the service or until any audit dispute or issue is resolved beyond six (6) years.

(b) After a recipient's death or discharge from services, a provider shall maintain the recipient's record for the longer of the following periods:

1. Six (6) years unless the recipient is a minor; or

2. If the recipient is a minor, three (3) years after the recipient reaches the age of majority under state law.

(c) If the Secretary of the United States Department of Health and Human Services requires a longer document retention period than the period referenced in paragraph (a) of this subsection, pursuant to 42 C.F.R. 431.17, the period established by the secretary shall be the required period.

(9)(a) A targeted case management services provider shall comply with 45 C.F.R. Part 164.

(b) All information contained in a case record shall:

1. Be treated as confidential;

2. Not be disclosed to an unauthorized individual; and

3. Be disclosed to an authorized representative of the:

a. Department;

b. Federal government; or

c. For an enrollee, managed care organization in which the enrollee is enrolled.

(c)1. Upon request, a targeted case management services provider shall provide to an authorized representative of the department, federal government, or managed care organization if applicable, information requested to substantiate:

a. Staff notes detailing a service that was rendered;

b. The professional who rendered a service; and

c. The type of service rendered and any other requested information necessary to determine, on an individual basis, whether the service is reimbursable by the department.

2. Failure to provide information referenced in subparagraph 1 of this paragraph shall result in denial of payment for any service associated with the requested information.

Section 10. Medicaid Program Participation Compliance. (1) A targeted case management services provider shall comply with:

(a) 907 KAR 1:671;

(b) 907 KAR 1:672; and

(c) All applicable state and federal laws.

(2)(a) If a targeted case management services provider receives any duplicate payment or overpayment from the department, regardless of reason, the targeted case management services provider shall return the payment to the department.

(b) Failure to return a payment to the department in accordance with paragraph (a) of this subsection may be:

1. Interpreted to be fraud or abuse; and

2. Prosecuted in accordance with applicable federal or state law.

(3)(a) When the department makes payment for a covered service and the targeted case management services provider accepts the payment:

1. The payment shall be considered payment in full;

2. A bill for the same service shall not be given to the recipient; and

3. Payment from the recipient for the same service shall not be accepted by the provider.

(b)1. A targeted case management services provider may bill a recipient for a service that is not covered by the Kentucky Medicaid Program if the:

a. Recipient requests the service; and

b. Targeted case management services provider makes the recipient aware in advance of providing the service that the:

(i) Recipient is liable for the payment; and

(ii) Department is not covering the service.

2. If a recipient makes payment for a service in accordance with subparagraph 1 of this paragraph, the:

a. Targeted case management services provider shall not bill the department for the service; and

b. Department shall not:

(i) Be liable for any part of the payment associated with the service; and

(ii) Make any payment to the targeted case management services provider regarding the service.

(4)(a) A targeted case management services provider attests by the targeted case management services provider signature that any claim associated with a service is valid and submitted in good faith.

(b) Any claim and substantiating record associated with a service shall be subject to audit by the:

1. Department or its designee;
2. Cabinet for Health and Family Services, Office of Inspector General or its designee;
3. Kentucky Office of Attorney General or its designee;
4. Kentucky Office of the Auditor for Public Accounts or its designee;
5. United States General Accounting Office or its designee; or
6. For an enrollee, managed care organization in which the enrollee is enrolled.

(c)1. If a targeted case management services provider receives a request from the:

a. Department to provide a claim, related information, related documentation, or record for auditing purposes, the targeted case management services provider shall provide the requested information to the department within the timeframe requested by the department; or

b. Managed care organization in which an enrollee is enrolled to provide a claim, related information, related documentation, or record for auditing purposes, the targeted case management services provider shall provide the requested information to the managed care organization within the timeframe requested by the managed care organization.

2.a. The timeframe requested by the department or managed care organization for a targeted case management services provider to provide requested information shall be:

(i) A reasonable amount of time given the nature of the request and the circumstances surrounding the request; and

(ii) A minimum of one (1) business day.

b. A targeted case management services provider may request a longer timeframe to provide information to the department or a managed care organization if the targeted case management services provider justifies the need for a longer timeframe.

(d)1. All services provided shall be subject to review for recipient or provider abuse.

2. Willful abuse by a targeted case management services provider shall result in the suspension or termination of the targeted case management services provider from Medicaid Program participation.

Section 11. Third Party Liability. (1) A targeted case management services provider shall comply with KRS 205.622.

(2) If a third party is liable to pay for targeted case management services, the department shall not pay for the services.

Section 12. Use of Electronic Signatures. (1) The creation, transmission, storage, and other use of electronic signatures and documents shall comply with the requirements established in KRS 369.101 to 369.120.

(2) A targeted case management services provider that chooses to use electronic signatures shall:

(a) Develop and implement a written security policy that shall:

1. Be adhered to by each of the targeted case management services provider's employees, officers, agents, or contractors;
2. Identify each electronic signature for which an individual has access; and
3. Ensure that each electronic signature is created, transmitted, and stored in a secure fashion;

(b) Develop a consent form that shall:

1. Be completed and executed by each individual using an electronic signature;
2. Attest to the signature's authenticity; and
3. Include a statement indicating that the individual has been notified of his or her responsibility in allowing the use of the electronic signature; and

(c) Provide the department, immediately upon request, with:

1. A copy of the targeted case management services provider's electronic signature policy;
2. The signed consent form; and
3. The original filed signature.

Section 13. Auditing Authority. The department or the managed care organization in which an enrollee is enrolled shall have the authority to audit any:

(1) Claim;

(2) Medical record; or

(3) Documentation associated with any claim or medical record.

Section 14. Federal Approval and Federal Financial Participation. The department's coverage of services pursuant to this administrative regulation shall be contingent upon:

(1) Receipt of federal financial participation for the coverage; and

(2) Centers for Medicare and Medicaid Services' approval for the coverage.

Section 15. Appeals. (1) An appeal of an adverse action by the department regarding a service and a recipient who is not enrolled with a managed care organization shall be in accordance with 907 KAR 1:563.

(2) An appeal of an adverse action by a managed care organization regarding a service and an enrollee shall be in accordance with 907 KAR 17:010. (41 Ky.R. 1263; Am. 1812; 1979; eff. 4-3-2015.)

908 KAR 2:260. Targeted case manager: eligibility and training.

RELATES TO: KRS 200.503(3), 210.005(2), (3)
STATUTORY AUTHORITY: KRS 194A.030, 194A.050, 210.450, 222.211
NECESSITY, FUNCTION AND CONFORMITY: KRS 194A.050(1) requires the secretary of the Cabinet for Health and Family Services to promulgate administrative regulations necessary to protect the health of Kentucky citizens and to implement programs mandated by federal law or to qualify for the receipt of federal funds. KRS 210.450 requires the secretary to promulgate administrative regulations governing qualifications of personnel and standards for personnel management for community programs for behavioral health or individuals with an intellectual disability. KRS 222.211 authorizes the cabinet to promulgate administrative regulations to assure that there is the provision of prevention, intervention, and treatment services for both juveniles and adults to address the problems of addiction to alcohol and other drug abuse within individuals, families, and communities. This administrative regulation establishes the minimum eligibility and training requirements for individuals providing behavioral health targeted case management services to a targeted behavioral health population.

Section 1. Definitions. (1) "Behavioral health practitioner under supervision" means an individual who is:
(a)1. A licensed professional counselor associate;
2. A licensed assistant behavior analyst;
3. A certified social worker;
4. A marriage and family therapy associate;
5. A licensed professional art therapist associate;
6. A physician assistant; or
7. A certified alcohol and drug counselor; and
(b) Employed by or under contract with the same billing provider as the billing supervisor.
(2) "Behavioral health professional" means:
(a) An advanced practice registered nurse as defined by KRS 314.011(7);
(b) A licensed clinical social worker as defined by KRS 335.100;
(c) A licensed marriage and family therapist as defined by KRS 335.300(2);
(d) A licensed professional clinical counselor as defined by KRS 335.500(3);
(e) A licensed psychological practitioner as defined by KRS 319.053;
(f) A licensed psychologist as defined by KRS 319.010(6) and 201 KAR Chapter 26;
(g) A licensed professional art therapist as defined by KRS 309.130(2);
(h) A physician as defined by KRS 205.510(11);
(i) A psychiatrist;
(j) A behavioral health practitioner under supervision;
(k) A registered nurse as defined by KRS 314.011(5) working under the supervision of a physician or advanced practice registered nurse;
(l) A certified alcohol drug counselor as defined by KRS 309.083;
(m) A certified psychologist as defined by 201 KAR Chapter 26;
(n) A certified psychologist with autonomous functioning as defined by KRS 319.056;
(o) A certified social worker as defined by KRS 335.080
(p) A licensed professional art therapist associate as defined by KRS 309.130(3);
(q) A licensed psychological associate as defined by KRS 319.010(6) and 201 KAR Chapter 26;
(r) A marriage and family therapy associate as defined by KRS 335.300(3);
(s) A physician assistant as defined by KRS 311.840(3);
(t) A licensed clinical alcohol and drug counselor as defined by KRS 309.080(4);
(u) A licensed clinical alcohol and drug counselor associate as defined by KRS 309.080(5); or
(v) An individual with a bachelor's degree in a behavioral science as defined in subsection (3) of this section who:
1. Is working under the supervision of a billing supervisor; and
2. Has at least five (5) years of documented full-time experience providing specialized case management services for the target population.
(3) "Behavioral science" means:
(a) Psychology;
(b) Sociology;
(c) Social work;
(d) Family studies;
(e) Human services;
(f) Counseling;
(g) Nursing;
(h) Behavioral analysis;
(i) Public health;
(j) Special education;
(k) Gerontology;
(l) Recreational therapy;
(m) Education;
(n) Occupational therapy;
(o) Physical therapy;
(p) Speech-language pathology;
(q) Rehabilitation counseling; or
(r) Faith-based education.
(4) "Case load" means the number of distinct individuals for whom a targeted case manager bills for services from any payor, per month.
(5) "Certification" means successful completion of the training requirements in this administrative regulation as documented by notice of successful training completion submitted to the department from the training provider.
(6) "Chronic or complex physical health condition" means that:
(a) Significant symptoms of a physical health condition have persisted in a client for a continuous period of at least six (6) months;
(b) The symptoms of the physical health condition significantly impair the client's ability to function:
1. Socially, or
2. Occupationally which, for individuals under the age of twenty-one (21), includes impairment in an educational setting; and
(c) The physical health conditions include disorders under the following categories:
1. Cardiovascular disorders;
2. Respiratory disorders;
3. Genitourinary disorders;
4. Endocrine disorders;
5. Musculoskeletal disorders;

6. Neurological disorders;
7. Immune system disorders;
8. Gastrointestinal;
9. Cancer; or
10. Hematological.

(7) "Client" means an individual identified within a target population.

(8) "Continuing education requirement" means successful completion of the on-going training requirements every three (3) years after the date of certification.

(9) "Core components" means the minimum knowledge and skills listed in Section 3(1) of this administrative regulation that an individual must demonstrate in order to successfully complete the training and meet eligibility requirements to provide targeted case management services.

(10) "Department" means the Department for Behavioral Health, Developmental and Intellectual Disabilities (DBHDID).

(11) "Face-to-face" means in person, in the same location, and not through an electronic method.

(12) "Serious mental illness", "severe mental illness", or "SMI" means a diagnosis of a major mental disorder as included in the current edition of the Diagnostic and Statistical Manual of Mental Disorders under:

(a) Schizophrenia spectrum and other psychotic disorders;
(b) Bipolar and related disorders;
(c) Depressive disorders; or
(d) Post-traumatic stress disorders (under trauma and stressor related disorders).

(13) "Severe emotional disability" or "SED" is defined by KRS 200.503(3).

(14) "Substance use disorder" or "SUD" means a primary moderate or severe substance use disorder diagnosis or co-occurring moderate to severe substance use disorder and mental health diagnosis as defined in the current edition of the Diagnostic and Statistical Manual of Mental Disorders.

(15) "Targeted case management services" means services furnished to assist a client in gaining access to needed medical, social, educational, or other needed services and supports, including:

(a) Assessment of the client's medical, social, and functional status and identification of the client's strengths and needs;

(b) Arranging for service delivery from the client's, the client's legal guardian, or the client's custodial parent's chosen provider to insure access to required services;

(c) Facilitating access to needed services by explaining the need and importance of services in relation to the client's condition;
(d) Facilitating access, quality, and delivery of necessary services; and
(e) Preparation and maintenance of case record documentation to include care plans, forms, reports, and narratives as appropriate.

(16) "Targeted case manager" means an individual who is:

(a) Trained and supervised to perform targeted case management services in accordance with Section 2 of this administrative regulation;
(b) Responsible for conducting a comprehensive assessment and a periodic reassessment of an individual's strengths and needs; and
(c) Responsible for assisting an individual to gain access to identified medical, social, educational, and other service needs.

(17) "Targeted population" means an individual who meets the criteria through diagnosis, duration, and disability for:

(a) SMI;
(b) SED;
(c) SUD; or
(d) SMI, SED, or SUD and a co-occurring chronic or complex physical health condition.

(18) "Training curriculum" means a total package of learning activities designed to achieve the goals of the training program with:

(a) The objective that trainees will acquire the specific knowledge and skills (competencies) needed to perform the duties of a targeted case manager; and

(b) Four (4) primary components, including:
1. Content or information to be transmitted, including:
a. Theoretical framework;
b. Conceptual rationale;
c. Best standards of practice;
d. Application to direct practice; and
e. Congruence between and within sections;
2. Organization of the curriculum, including structure, format, and sequencing, incorporating:
a. Concordance with the natural learning process;
b. Design of each section linked to specific learning objectives, with adequate time provided for each;
c. Linkages between sections;
d. Knowledge and skills that are conceptually related, or that are performed together on the job, are taught together; and
e. Retention and understanding facilitated by principles of sequencing (from simple to complex, from the universal to the exception, and from fundamental to more refined applications) and repetition;
3. Training methods appropriate to adult learners in an applied setting, in each section or topic area, including:
a. Discussion to promote exploration and understanding of the topic;
b. Experiential exercises or simulations; and
c. Presentation of the same concepts using a variety of learning strategies (for example, hearing, seeing, modeling, and then practicing) to ensure that trainees with different learning styles can assimilate the knowledge; and
4. Evaluation methods, including:
a. Trainee knowledge assessment through testing, with achievement of a passing aggregate assessment score of at least seventy (70) percent; and
b. Trainee performance reviews of trainers.

Section 2. Targeted Case Manager Requirements. (1) A targeted case manager for individuals with SMI, SED, or SUD shall:

(a)1. Possess a bachelor of arts or science degree in a behavioral science;
2. Be a certified alcohol and drug counselor who has a bachelor of arts or science degree;
3. Have provided targeted case management services to a recipient any time from April 1, 2014, to the effective date of this administrative regulation; or
4. Have supervised the provision of targeted case management services to a recipient any time from April 1, 2014, to the effective date of this administrative regulation;

(b) Have at least one (1) year of full-time employment experience after completing the educational requirements:
1. Working directly with adults in a human service setting; or
2. Working directly with individuals under the age of twenty-one (21) in a human service setting;

(c) Successfully complete a department approved targeted case management training within six (6) months of employment as a targeted case manager; and

(d) Successfully complete department approved continuing education requirements every three (3) years thereafter.

(2) A master's degree in a behavioral science may substitute for the one (1) year of full-time employment experience required by subsection (3)(b)1 of this section.

(3) A targeted case manager for individuals with SMI, SED, or SUD and a co-occurring chronic or complex physical health condition shall be an individual with:

(a) A master's degree in a behavioral science from an accredited college or university and two (2) years of full-time employment experience providing service coordination or linking/referring for community based services for individuals with SMI, SED, or SUD and co-occurring physical or behavioral health disorders or multi-agency involvement; or

(b) A bachelor of arts or science degree from an accredited college or university in a behavioral science and who has:

1. At least five (5) years of full-time employment experience working with an individual with SMI, SED, or SUD and a co-occurring chronic or complex physical health condition;

2. Successful completion of a department approved targeted case management training within six (6) months of employment as a case manager; and

3. Successful completion of continuing education requirements every three (3) years thereafter.

(4) Targeted case managers who are serving individuals with SED, SMI, or SUD shall have:

(a) Individual face-to-face supervision which shall be provided at least monthly for at least one (1) year by a behavioral health professional who has completed the targeted case management training approved by the department; and

(b) Group supervision which shall be provided at least monthly for the duration of employment as a targeted case manager.

(5) The supervisor of a targeted case manager shall maintain documentation of the supervision.

(6) Targeted case managers who are serving an individual with an SED, SMI, or SUD and a co-occurring chronic or complex physical health condition shall have:

(a) Individual supervision which shall be provided at least three (3) times per month, with at least two (2) of these supervisory contacts on an individual face-to-face basis, for at least three (3) years by a behavioral health professional who has completed the targeted case management training approved by the department; and

(b) Group supervision which shall be provided at least monthly for the duration of employment as a targeted case manager.

(7) Beginning October 1, 2015, a targeted case manager shall not exceed a case load size of twenty-five (25) unique clients receiving any service, excluding a client receiving mobile crisis services, crisis intervention services, or screenings.

(8) A targeted case manager shall:

(a) Only provide targeted case management services to the targeted population for which the targeted case manager meets the educational, experiential, and training requirements; and

(b) Not provide other behavioral health services in addition to targeted case management services for the same client.

Section 3. Training Requirements. (1) To receive certification to provide behavioral health targeted case management services, a targeted case manager shall successfully complete the department approved training and continuing education requirements established by this section.

(a) The core components of the targeted case management training curriculum shall be at least twelve (12) hours and shall include:

1. Core targeted case management functions and guiding principles;
2. Engaging consumers and family members;
3. Behavioral health crisis management;
4. Strengths-based case management;
5. Ethics;
6. Behavioral health diagnosis and understanding treatment;
7. Integrated care;
8. Advocacy skills and empowering consumers and families;
9. Cultural awareness;
10. Developmental perspectives across the life span; and
11. Documentation and billing.

(b) At least an additional six (6) hours of specialized training for the target population the targeted case manager is serving, which shall include the skills required to address the specific needs of each respective target population.

(c) Providers of approved training curricula shall notify the department within twenty (20) business days of a trainee's successful completion of a targeted case manager training.

(2) A targeted case manager shall complete continuing education requirements every three (3) years.

(3) Required continuing education shall consist of acquiring at least six (6) hours of relevant continuing education each year in training topics directly related to:

(a) Case management;

(b) Behavioral health; or

(c) Each respective target population.

(4) A targeted case manager shall submit a list of all continuing education trainings in which the targeted case manager participated, the provider or presenter of the training, and the number of hours of each training to the Department every three (3) years through the department's Web site. The submission due date shall be the last day of the month of which the targeted case manager's initial certification was completed.

(5) Targeted case managers certified prior to the effective date of this administrative regulation shall submit documentation of continuing education hours prior to May 2018.

Section 4. Department Responsibilities. The department shall:

(1) Within twenty (20) business days, approve or deny training curricula submitted by providers wishing to provide training to a targeted case manager or a prospective targeted case manager based on the training curriculum requirements established by Section 3(1)(a) of this administrative regulation;

(2) Maintain a record of approved targeted case management training curricula, including contact information for providers of the trainings on the department's Web site;

(3) Maintain a record of targeted case managers who have received a certificate of successful completion of a department approved targeted case management training on the department's Web site;

(4) Create and make available a process for recording continuing education of targeted case managers on the department's Web site; and

(5) Maintain a record of targeted case managers who have been certified or completed continuing education to provide targeted case management services on the department's Web site.

Section 5. Supervision of a Targeted Case Manager. (1) A targeted case manager shall provide services under the supervision of a behavioral health professional in accordance with 907 KAR 15:040, 907 KAR 15:050, and 907 KAR 15:060;

(2) The supervising behavioral health professional shall complete the training requirements as described in Section 3(1) and (2) of this administrative regulation; and

(3) The supervisor of a targeted case manager shall provide and maintain documentation of the supervision, as specified in Section 2(4), (5), and (6) of this administrative regulation. (41 Ky.R. 1945; Am. 2280; 2656; eff. 6-17-2015, TAm eff. 4-27-2016.)

Add to ARTICLE 5Y. MEDICATION-ASSISTED TREATMENT PROGRAM LICENSING ACT §16-SY-2. Definitions

"Targeted case manager" means an individual who is:

(a) Responsible for conducting a comprehensive assessment and a periodic reassessment of an individual's strengths and needs; and

(b) Responsible for assisting an individual to gain access to identified medical, social, educational, and other service needs.

(c) Responsible for coordinating services to providers in the community

(d) Responsible for developing care plan goals in accordance with an individual service plan

"Targeted case management services" means services furnished to assist a client in gaining access to needed medical, social, educational, or other needed services and supports, including:

(a) Assessment of the client's medical, social, and functional status and identification of the client's strengths and needs;

(b) Arranging for service delivery from the client's, the client's legal guardian, or the client's custodial parent's chosen provider to insure access to required services;

(c) Facilitating access to needed services by explaining the need and importance of services in relation to the client's condition;

(d) Facilitating access, quality, and delivery of necessary services; and

(e) Preparation and maintenance of case record documentation to include forms, reports, and narratives as appropriate.

Modify §69-12-2, **Definitions** 2.6 to include Targeted case manager, ~~"the process of coordinating and monitoring the services provided to a patient both within the program and in conjuncture with other providers~~. And Targeted case management services based of **§16-SY-2. Definitions.**

Add 7.6 to include Targeted Case Management Staff

Add 7.6.1 to include Targeted Case Manager Requirements. (1) A case manager shall:

(a)1. Have at least a bachelor of arts or science degree in a behavioral science and

(b.) One year of experience in the substance use disorder field

Add 7.6.2 Reimbursement. (1) The department shall reimburse a monthly rate of $334 in total for all targeted case management services provided to a recipient during the month.

(2) to qualify for the reimbursement referenced in subsection (1) of this section, a targeted case management services provider shall provide services to a recipient consisting of at least four (4) targeted case management service contacts including:

(a) At least two (2) face-to-face contacts with the recipient; and

(b) At least two (2) additional contacts which shall be:

1.a. By telephone; or

b. Face-to-face; and

Modify administrative regulation to include grammatical and citation amendments throughout as well as technical renumbering throughout.

Suggestions Based of Kentucky Administrative Regulations

908 KAR 2:260. Targeted case manager: eligibility and training.

907 KAR 15:040. Coverage provisions and requirements regarding targeted case management for individuals with a substance use disorder.

907 KAR 15:045. Reimbursement provisions and requirements for targeted case management services for individuals with a substance use disorder.

(see regulations attached)

Circumstances and Rationale

Targeted case management (TCM) provides services to build resilience, and to support the recovery or well-being of individuals and the integration of individuals served into the community. Through service provision, symptoms or needs will be reduced and individuals will experience an improvement in level of functioning in their environment. The program strives to continually improve service provision in order that individuals served experience an enhanced quality of life.

The goal of Targeted Case Management services is to provide goal-oriented and individualized services that focus on increasing independence and self-sufficiency for the persons served through assessment, planning, linking, advocacy, coordination and monitoring activities. An increase in independence and community inclusion opportunities for persons served is the result of successful case management/supports coordination.

Services are based on the needs and choices of the person served and with their participation in treatment planning and service provision case management/supports coordination includes: coordination of services, follow-up, monitoring, referral, outreach, facilitation of activities which promote community inclusion, assistance with community linkage and enhanced social support networks, coordination of assistance with crisis intervention and stabilization services, assistance with accessing transportation, exploring employment or other meaningful activities, and advocacy. A person centered treatment approach is used to help identify the individual's strengths, dreams, goals, and desires.

Populations served include individuals with SUD/co-occurring disorders, who have multiple service needs, have a high level of vulnerability, require access to a continuum of mental health services, and/or are unable to independently access and sustain involvement with needed services. Services are provided in the location that best meets the need of the service being provided (i.e., at the agency, individual's home, community) based on the choice of the person served.

Lawson, Kathy M

From: Paul, Lisa <Lisa.Paul@hsc.wvu.edu>
Sent: Thursday, July 19, 2018 8:52 AM
To: Lawson, Kathy M
Subject: In reference to WV State Rule of MAT treatment in office based settings
Attachments: 2018_07_19_07_23_46.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Dear Inspector General Lawson,

I am sending you a copy of a letter written by Dr. James Berry in reference to the state rule for prescribing MAT in office base settings.

I am in agreement with Dr. Berry's comments and am hopeful his comments will be taken into consideration on MAT treatment provisions and access in West Virginia.

Thank you,

Lisa C Paul MSW, LICSW

Outpatient Clinical Therapist
Department of Behavioral Medicine and Psychiatry
WVU Medicine
Morgantown, WV
304-598-4214

Lawson, Kathy M

From: Chiasson-Downs, Kathleen <kchiasson@hsc.wvu.edu>
Sent: Thursday, July 19, 2018 1:51 PM
To: Lawson, Kathy M
Subject: regarding the proposed changes for MAT prescribing practices
Attachments: public comments letter.pdf

Follow Up Flag: Flag for follow up
Flag Status: Flagged

Greetings, Ms. Lawson, my name is Kathleen Chiasson-Downs, and I am a clinical therapist at with the WVU Department of Behavioral Medicine in Morgantown, WV. I am writing to you today to statement my official agreement with the attached letter, written by my colleague, Dr. James Berry. I agree with all of his points and suggestions made, and look forward to the final ruling on this matter.

Thank you for all you do,

Kathleen Chiasson-Downs, LPC, ALPS, AADC
WVU Department of Behavioral Medicine
P.O. Box 9137 Morgantown, WV 26505
304-293-7723

"Be kinder than necessary, for everyone you meet is fighting his or her own battle."

Lawson, Kathy M

From: Cunningham, Jordan <jcunni12@wvumedicine.org>
Sent: Thursday, July 19, 2018 2:08 PM
To: Lawson, Kathy M
Subject: Public comment for 69CSR12
Attachments: 2018_07_19_07_23_46.pdf

Follow Up Flag: Flag for follow up
Flag Status: Flagged

Dear Inspector General Lawson,

I wanted to send my support of the attached letter written by our Director of Addictions Dr. James Berry. As described eloquently in the attached letter we need start removing barriers put in front of those seeking help with substance use disorders and subsequently destigmatizing those afflicted with this disease. I hope you will highly consider removing these barriers to scientifically proven treatment modalities , so that we as healthcare providers can effectively treat our patients . In this time of great need we need to consider bringing more healthcare providers into the realm of addiction medicine, rather than deterring potential providers with unnecessary bureaucracy. I have personally been a part of changing the lives of hundreds of our patients suffering from addiction and know that treatment/recovery is possible if the necessary tools are provided to the individual. Access to care is one of the biggest problem facing addiction medicine and we should be focused on expanding care vs. exacerbating the issue at hand by further limiting treatment availability.

West Virginia has a myriad of healthcare professionals, such as myself, who are willing to help curtail this epidemic so I implore you to work with us in establishing policies/procedures to attain best treatment outcomes.

Sincerely,

Jordan Cunningham MPA
Telepsychiatry Case Manager
West Virginia University Medicine
Department of Behavioral Medicine & Psychiatry
Telepsychiatry Program
930 Chestnut Ridge Road
Morgantown, WV 26505
304.293.5126
cunninghamj2@wvumedicine.org
Fax: 304.293.9312

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Lawson, Kathy M

From: Zafar, Jawad <jzafar@osteo.wvsom.edu>
Sent: Thursday, July 19, 2018 8:13 PM
To: Lawson, Kathy M
Subject: MAT
Attachments: attachment 1.pdf; ATT00001.htm

Follow Up Flag: Flag for follow up
Flag Status: Flagged

As a psychiatrist treating addiction in private practice I agree with the comments and changes referred in this letter. We need to increase access and treatment for patients suffering from opioid addiction.

Lawson, Kathy M

From: Parks, Joy <jparks6@hsc.wvu.edu>
Sent: Thursday, July 19, 2018 8:59 PM
To: Lawson, Kathy M
Subject: Regarding 69CSR12
Attachments: 69CSR12.pdf

Follow Up Flag: Flag for follow up
Flag Status: Flagged

Dear Inspector General Lawson,

I would like to second the sentiment shared in the letter Dr. Berry sent you (see attached). Opioid use disorder is a huge problem in WV and undo burden need not be imparted on those clinicians trying to treat this already stigmatized condition.

Thank you,
Joy Parks, MD
Department of Psychiatry
West Virginia University

Lawson, Kathy M

From: Steven Knudsen <stevo1279@gmail.com>
Sent: Thursday, July 19, 2018 9:08 PM
To: Lawson, Kathy M
Subject: substance use disorder -- proposed rule making
Attachments: SUD_Lawson.pdf

Follow Up Flag: Flag for follow up
Flag Status: Flagged

Ms. Lawson,

I have read and concur with the attached letter regarding substance use disorder -- proposed rule making/comment period. I encourage liberalization of current rules to turn the rate of death due to opioid abuse/overdose sharply down, and this letter lays out a path to that end.

Thank you.

Steve K.

Lawson, Kathy M

From: Quigley, Brian <bquigley@hsc.wvu.edu>
Sent: Friday, July 20, 2018 9:08 AM
To: Lawson, Kathy M
Subject: Medication Assisted Treatment
Attachments: 69CSR12.pdf

Follow Up Flag: Flag for follow up
Flag Status: Flagged

Dear Inspector Lawson,
Please consider the carefully thought out letter written by Dr. James Berry that discusses the rational and importance for making Medication Assisted Treatment available to patients in West Virginia. I am in agreement and hope the letter can have an impact on future discussions and decisions in this area.

Sincerely,
Brian Quigley

Brian Quigley MD
Assistant Professor
Department of Behavioral Medicine and Psychiatry WELLWVU Director of Psychiatry The Students' Center of Health The Carruth Center for Psychological and Psychiatric Services West Virginia University

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Lawson, Kathy M

From: Bruce Gorby <erdrbag@icloud.com>
Sent: Friday, July 20, 2018 9:25 AM
To: Lawson, Kathy M
Subject: Dr Berry Letter

I agree with all that Dr Berry said.
We need to do something ASAP
Hundreds of people are dying every day and we have effective treatment.
Please allow us to utilize it without making it so cumbersome.
Respectfully
Dr Bruce Gorby

Sent from my iPhone

Lawson, Kathy M

From: Miller, Mark <mark.miller1@hsc.wvu.edu>
Sent: Friday, July 20, 2018 9:28 AM
To: Lawson, Kathy M
Subject: Endorsement of letter by Colleague Jim Berry

I fully agree with the points s outlined by Jim Berry in the letter reproduced here. All of us psychiatrists struggle with finding ways to treat our OUD patients without undo leagal restictions that limit our effectiveness.

WestVtrginiaUniversity.

July 18, 2018

Kathy Lawson, Inspector General
State Capitol Complex
Building 6, Room 817
Charleston, WV 25305

RE: Public comment for 69CSR12

Dear Inspector General Lawson,

Prior to offering my recommendations regarding the legislative rule, I believe it is important to provide the history,context and purpose of office based buprenorphine treatment.

Prior to the Drug Abuse Treatment Act of 2000, the only opioid agonist medication permitted to treat Opioid Use Disorder (OUD) was methadone. Methadone treatment was (and continues to be) highly regulated by state and federal authorities. An unintended consequence of the regulation was to segregate Substance Use Disorder (SUD) treatment from general medical care as treatment could only occur in designated methadone clinics. This severely limited access to treatment and added to the stigma of SUD. A person suffering from this disease could not access an evidence-based medication in their doctor's office. Please note, it wasn't the medication itself that motivated the regulations, rather it was the disease: Addiction . Doctors were (and still are) allowed to prescribe methadone in their offices for pain, just not for SUD.

As the growing tide of OUD became apparent in the late nineties,health authorities realized physicians needed a tool to manage severe opioid cravings and withdrawal in their own offices.
Buprenorphine was selected based on it's unique pharmacologic properties as a partial opioid agonist and a decade's worth of evide nce demonstrating safety and efficacy in France. The intent was not to silo SUD treatment any longer but equip physicians to treat SUD as they would any other chronic disease .

The clinician is required to achieve special training requirements and obtain a waiver from the DEA. Like methadone, this was required not because of any inherent danger beyond other controlled substances, rather because it would be used to treat SUD.

The context today is that physicians may prescribe every legal controlled substance as part of their routine medical practice. Physicians undergo four years of medical school as well as several years of medical residency training and life-long continuing education activities in order to be sufficiently equipped to do so.They are regulated by state medical licensing boards to ensure practice meets the standard of care . They are further regulated by the DEA to ensure safety.

As a licensed physician in West Virginia, I can prescribe an unlimited supply of Neurontin, Xanax and Adderall to as many patients who may request them.There are no additional rules required by legislators or state agents requiring such items as referral to vocational training or specify ing the arrangements needed to be made when I go on vacation. There is no senate bill mandating an inspection by OHFLAC or exte nsive reporting requirements. Each one of these medications mentioned DEPARTMENT OF BEHAVIORAL MEDICINE AND PSYCHIATRY PO Box 9137 I 930 Chestnut Ridge Rd Morgantown. WV 26506 [;] 304.293.5323 D 304.293.8724

above is diverted and sold on the street. The difference is these are not used to treat SUD. Once again, the disease is discriminated aga inst. Why further stigmatize those patients who actually are brave enough to admit they have a problem by placing burdens on providers not required for prescribing controlled substances for other conditions?

Buprenorphine is a life saving medication. This is no hyperbole. The fact is well-documented in the scientific literature and borne out in my clinical experience treating patients with the medicine for the past 14 years. Every major medical society and national health agency acknowledges that ready access to MAT is essential for curbing the opioid addiction crisis. These agencies have a unified message:
eliminate barriers preventing immediate and ongoing access to responsible buprenorphine prescribers.
Accordingly, most states have eased these burdens. West Virginia has the most restrictive legislative requirements codified in state law. This is tragic since West Virginia leads the nation in opioid overdose deaths.

Imagine if the same state rules required for buprenorphine were required for insulin, another life saving medication. Insulin should be properly thought of as medication assisted treatme nt for type
2 diabetes . For most, dietary counseling and exercise therapy plus medication is optimalto achieve best results. West Virginia has one of the highest rates of diabetes in the country, which may also be legitimately described as an epidemic. It would truly be a tragedy if physicians were in any way hampered from providing this necessary treatment. One sure way to hamper physician engagement would be to legislate down to the finest detail how the treatme nt must be conducted. Especially if this is not based on scientific evidence or expert consensus. Another certain way to minimize physician engagement wou ld be to add additional application fees, mandate burdensome reporting requirements and subject offices to site examinations.

Because many doctors are liable to the same prejudices regarding SUD as the genera l population, they are not quick to sign up to treat this disease. The prospect of adding a significant economic and time burden to do so is simply too much for most.

At the same time, the reality of buprenorphine diversion must be acknow ledged. Measures should be in place to minimize this diversion and support providers who prescribe responsibly. The cha llenge is to achieve the proper balance of regulation versus access. Iappreciate the Department of Health and Human Resources effort to attempt this balance

'by recognizing the overly prescriptive nature of the originally drafted rule. Istrongly support all the recommended deletions in the current draft.
In addition, I recommend the following changes:

1. Remove the reporting requirements in 13.2 and 13.3. These reporting requirements are unnecessary and overly burdensome. I support keeping records of adverse events and policies on how to deal with these as part of any routine medical practice. I do not believe it is necessary to report these to the state.
2. Remove 19.3 regarding age requirement. Buprenorphine is approved for patients 16 years and older. The strict requirement of an application to the state opioid treatment authority would limit access to adolescents who acutely need this medication in order to reduce overdose risk and engage in treatment.

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WestVrrginiaUniversity.

3. Remove 20.2. This is not clear on how a program is to "check the records of opioid treatment programs to ensure that the patient is not currently enrolled in those programs as well."
Certainly, this would rarely be practicable on a routine basis. There is no current mechanism to do so. The only way a prescriber would know if a patient has been enrolled in another program is if the patient divulges this information or the medication is listed on the controlled substances monitoring program database.
4. Remove 22.1. Providing or referring to vocational and educational services, although of value, is beyond the scope of basic best medical practices and beyond accepted MAT guidelines.
5. Remove 26.5. Obtaining a negative pregnancy screen on all female patients administratively withdrawn from the program is not possible. Some patients are withdrawn for not presenting to the program. Some are withdrawn for not complying with the rules of the program and are unwilling to consent for a pregnancy screen.
6. Addend 28.1 and 28.2.4a. Remove the monthly requirement for drug testing for patients who have demonstrated long-term stability. For example, a patient who has been compliant with treatment for three years and engaged in normal, busy life activities. Now healthy, she is consumed with work and family responsibilities and lives far away from her treatment provider. Having her present monthly is an undue burden.The frequency of screens for these long-term patients with demonstrated stability should be at the discretion of the provider.
7. Addend 28.2.2 to state "...have the capability of obtaining medication and or metabolite levels through biologic screening when clinically indicated or through random testing." Blood levels are not necessary as these can be obtained in urine.
8. Addend 28.2.9 to strike out "opiates" and finish the sentence as "...elimination of substances."
9. Remove the stigmatizing language of "opioid-addicted pregnant women" in 29.5.3 and replace with "pregnant women with active opioid use disorder."
10. As above, in 29.5.5. a referral is not always possible in an administrative discharge as the patient may be lost to follow up or refuse the referral.

Ialso am greatly encouraged by the removal of clinicians treating thirty patients or less from this rule. Furthermore, I recommend an exemption be considered for those who are part of a state-recognized consortium of responsible MAT providers. As treatment demand continues to expand, so does the need to increase immediate access. An approved

'consortium may be created to provide formal, ongoing MAT-mentorship for clinicians in our communities who want to treat more than thirty patients, but are hindered by the current regulatory burden.

Sincerely,

James H. Berry D.O.

Associate Professor and Vice Chair
Director of Addictions

DEPARTMENT OF BEHAVIORAL MEDICIN E AND PSYCHIATRY PO Box 9137 I 930 Chestnut Ridge Rd Morgantown, WV 26506
m 304.293 .5323 11304.293.8724

Mark D. Miller M.D.
Dana Farnsworth Chair of Educational Psychiatry

Lawson, Kathy M

From: Lander, Laura <llander@hsc.wvu.edu>
Sent: Friday, July 20, 2018 9:59 AM
To: Lawson, Kathy M
Subject: Public comment for 69CSR12
Attachments: Letter to Inspector General.pdf

Dear Ms. Lawson,

I wanted to echo the comments and recommendations made by my colleague Dr. Berry in the letter attached.

I am SW faculty in the Department of Behavioral Medicine at WVU and work with patients in our MAT program here and have helped to develop and expand the program over the last 12 years that I have been here. I am also involved in the SAMSHA STR MAT expansion grant and have first-hand knowledge of the need for and impediments to MAT expansion.

WE know that MAT saves lives. We also know that it does not work for everyone and that diversion is a reality. I agree that it can be a challenge to balance regulation and access. I agree with all of Dr. Berry's recommendations for changes outlined in his attached letter.

Thanks so much for your consideration.

Laura R. Lander, MSW, LICSW
Associate Professor, Department of Behavioral Medicine and Psychiatry
West Virginia University
930 Chestnut Ridge Road
Morgantown, WV 26508

P-304-293-3965
F-304-293-8724
llander@hsc.wvu.edu

WVUMedicine

Lawson, Kathy M

From: Melvin, Kelly E. <melvin3@marshall.edu>
Sent: Friday, July 20, 2018 10:01 AM
To: Lawson, Kathy M
Subject: OBMAT regs
Attachments: 69CSR12.pdf

Ms. Lawson,

I provide office based MAT services at the Recovery Center in Huntington, WV. I simply wish to state my full support for the comments provided by Dr. Jim Berry in the attached letter. The current state legislation regulating OBMAT is too restrictive to allow sufficient medical treatment of the opioid use epidemic.

I sincerely appreciate your time and support on this matter.

Kelly Melvin, MD
Associate Professor, Clerkship Director
Department of Psychiatry and Behavioral Medicine
Marshall University Joan C Edwards School of Medicine
1115 20th street, suite 205
Huntington, WV 25703
(304)691-1555 - office

Lawson, Kathy M

From: Bonnie Strayer <bs0060@mix.wvu.edu>
Sent: Friday, July 20, 2018 10:51 AM
To: Lawson, Kathy M
Subject: Public Comment on 69CSR12
Attachments: 69CSR12.pdf

Dear Ms. Lawson,

Attached, please find a letter composed by Dr. Jim Berry. I agree with all comments and amendments outlined in this letter.

In addition, I encourage the amended version of 69CSR12 to stop singling out females living with active opioid use disorder because of their unique ability to conceive a child. The amended version should also address the fathers of children in utero who are living with active opioid use disorder.

Thanks you,

Bonnie Strayer, LSW

Lawson, Kathy M

From: Aromin, Jourdan <jaromin@hsc.wvu.edu>
Sent: Friday, July 20, 2018 11:29 AM
To: Lawson, Kathy M
Subject: MAT office based treatment regulations
Attachments: 69CSR12.pdf

Greetings,

My name is Jourdan Aromin and I am Chief Resident of Behavioral Medicine and Psychiatry at WVU. I was recently made aware of upcoming legislation in regards to office based medication assisted treatment. I understand that there has been a newly revised draft regarding MAT that is currently in the public comment period until Saturday. I have reviewed this draft, which has raised a multitude of concerns with its current iteration. I am attaching a letter written by Dr. Berry, our head of addictions at WVU, which carefully points out all of the concerns I also share.

Although I am sure you are completely aware, the current opioid epidemic is taking more and more lives every day from West Virginians. As a native from this state and someone who has continued all of my education in Morgantown, it is disheartening to continue to see our people suffer. Access to medication assisted treatment needs to be more readily available in order to save lives from fatal overdoses, return overall day to day functioning to the ill, and also to stay ahead of potential infectious disease outbreaks such as HIV and hepatitis.

This is a medical illness with medical studies that have demonstrated time and time again that MAT is a gold standard for effective treatment of opioid use disorder. Again, I agree with all of the points Dr. Berry has mentioned in the attached file.

Regards,

Jourdan Aromin MD

Jourdan Aromin MD
PGY4 Chief Resident, Behavioral Medicine and Psychiatry
West Virginia University
Morgantown, WV 26505
jaromin@hsc.wvu.edu