Bagby, Tammy (LARA)

From: Moreno, Jessica L <Jessica.Moreno@beaumont.org>
Sent: Wednesday, August 24, 2022 1:30 PM
To: LARA-BCHS-Training
Subject: Comments on LARA Draft Rules for Substance Use Disorder Service Programs

Good Afternoon,

My name is Jessica Moreno and I am a Psychiatric Clinical Pharmacy Specialist with Beaumont Health. I have been working in mental health and substance use disorder for the past 8 years. I was glad to see that there will be an update to LARA's rules for substance use disorders service programs and I would like to provide several comments in hopes of further improving the current draft.

1. Overall, the document continues use of the term "medication-assisted treatment;" however, this term is now considered outdated and stigmatizing. Medications for addiction treatment are life-saving interventions; they do not "assist" in addiction treatment, they ARE addiction treatment. An alternative that still permits use of the acronym "MAT" would be "medications for addiction treatment."
2. I strongly support striking Rule 325.1303(3)(c) as until now, this rule has served as a significant barrier to evidence-based addiction treatment.
3. I strongly support the authorization of mobile and branch units to expand access to treatment (Rule 325.1304); however, it is not clear why a branch would be limited to being open only 20 hours per week (Rule 325.1304(4)(b)) or why it must be within 75 miles of the parent location (Rule 325.1304(4)(d)). These additional limitations simply limit access to treatment. Michigan has an extreme shortage of SUD treatment providers outside of urban areas so branch units should be permitted to operate to meet the needs of their localities.
4. It is excellent that treatment facilities will be required to discuss potential benefits and risks of all treatment options available (Rule 325.1331(2)(d)); however, I strongly encourage LARA and/or MDHHS to compose a standard informed consent document covering this information so we can be sure that treatment programs are communicating consistent and truthful information to potential recipients.
5. I strongly support the discouragement of discharge solely for return to use (Rule 325.1331(2)(e)). Changing this practice should significantly lower the risk of poor health outcomes and death for people who use drugs.
6. I strongly support requiring programs to offer naloxone to their recipients (Rule 325.1331(2)(f)) as this is a solution that should be very easy to implement and will lower risk of death from overdose.
7. I am glad to see the prioritization of evidence-based services for residential programs (Rule 325.1385(8)), though I recommend including guidance on what specifically those services are. Many treatment programs say they provide evidence-based care and then do nothing of the sort.
8. I do not support the permission of "clinically managed withdrawal management services" as they are defined in Rule 325.1388(2) as there is no place in evidence-based withdrawal management for not permitting any medication treatment (current draft states "shall offer peer and social support services only"). Substance withdrawal can be extremely dangerous and deadly and should only ever be managed under the supervision of qualified clinicians in medical settings with the capacity to manage medical emergencies. The criteria listed under Rule 325.1388(5)(a) are too narrow in scope and still permit significant risk to recipients who fall outside of these criteria.

Thank you for your time,

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MHA Michigan Health & Hospital Association | Leading Healthcare

August 30, 2022

Tammy Bagby
Licensing and Regulatory Affairs
611 West Ottawa Street
Lansing, MI 48909

RE: Proposed Rule Set 2021-90 LR Substance Use Disorder Service Programs

Dear Ms. Bagby:

On behalf of Michigan hospitals, the Michigan Health & Hospital Association (MHA) appreciates the opportunity to provide comments on the proposed rule set 2021-90 LR Substance Use Disorder (SUD) Service Programs.

The MHA supports updating the methadone treatment program rules to adhere to federal standards, which will reduce the required drug tests from 18 to 9 during year one treatment and 12 to 8 drug tests for year 2. The MHA supports the proposed removal of the requirement that currently limits prescribing buprenorphine or naltrexone to 100 individuals at a single time for medication assisted treatment. We also support the exclusion of these programs from the proposed rule which, as proposed, would only regulate methadone programs. These changes will improve patient care access by aligning state and federal standards and deregulating medication access of buprenorphine and naltrexone.

The MHA supports the addition of limited certified counselors to provide outpatient counseling services to patients receiving SUD services and requests the department continuously evaluate R 325.1381 (6), the 1 to 32 limited certified counselor-to-recipient ratio to ensure patient access isn't being unnecessarily restricted. **The MHA requests the department analyze the Wisconsin SUD 1 to 50 limited certified counselor-to-recipient ratio and evaluate if a similar model would benefit Michigan patient access for SUD programs.**

The MHA supports the addition of mobile units to expand patient access and requests clarification on limiting the number of branch offices and mobile units to 3. **The MHA requests the department reevaluate limiting branch and/or mobile units if a parent organization has the staffing, resources, and community demand to provide more than 3 branch and/or mobile units.**

Please contact me at rsmiddy@mha.org if you have any questions regarding these comments or if you need additional information.

Sincerely,

Renée Smiddy
Sr. Director, Policy

Jessica L. Moreno, PharmD, BCPP
She/Her/Hers
Psychiatric Clinical Pharmacy Specialist
Integrated Behavioral Health
Beaumont Medical Group
Cell: (248) 497-1690

THE PROVIDER ALLIANCE
4507 SOUTH GRAND AVE, LANSING, MI 48933

TO: Larry Horvath, Bureau of Community and Health Systems,
Department of Licensing and Regulatory Affairs

DATE: August 31, 2021

The SUD agencies within the Provider Alliance express their gratitude to LARA for the dialogue during the last several years in an extended review of the Administrative Rules. There are many progressive additions and deregulations that we are very supportive of, and appreciate the work that has gone into these. This includes items like the addition of branch offices and mobile units, simplifying the rules around Medication Assisted Treatment, and the return of clinically managed (social detox) withdrawal management programs.

During this season of public comment for the proposed rule changes, there are a few items that we would still request your attention to:

R 325.1301 Definitions.

(f) ~~"Community change, alternatives, information, and training" or "CAIT" means prevention services offered by a substance use disorder services program.~~

COMMENT: (f) We continue to express the concern that removing a licensing requirement opens up our communities to agencies that do not use trained professionals or evidence-based programming.

(u) "Limited certified counselor" means an individual who is employed or who volunteers to work providing counseling to recipients in a substance use disorder services program licensed by the department under part 62 of the public health code, MCL 333.6230 to 333.6251, and who has completed a minimum set of state-approved requirements before completing the necessary prerequisites to become a certified alcohol and drug counselor by an organization approved or recognized by the department.

COMMENT – (u) What are the state approved requirements?

(w) "Methadone program" means a program engaged in opioid treatment of an individual with an opioid agonist treatment medication registered under 21 USC 823(g)(1), methadone.

COMMENT - (w) Suggest referring to a program as an Opioid Treatment Program. This is the national recognition for a program that provides methadone. A provider cannot utilize methadone without obtaining federal certification called Opioid Treatment Program. Referring to a program as a "Methadone Program" is archaic and contributes to unnecessary stigma associated with the term methadone.

R 325.1309 Waiver from licensure survey.

(1) The department shall provide and make publicly available a procedure for when a licensee may be eligible for a waiver from a licensure survey. The procedure must include maintaining a list of approved accrediting bodies for programs.
(2) On or before October 1 of each year, the department shall publish a list of programs to receive a licensure survey in the next calendar year.
(3) An eligible licensee may request a waiver from licensure survey on or before November 1 of each year. A waiver request shall be submitted on a form authorized by the department.
(4) On or before January 1 of the survey year, the department shall provide in writing an approval or denial of the waiver from licensure survey to the licensee.

COMMENTS – Has the Department completed the procedure to request a waiver and made that publicly available?

Rule 1331Policies and Procedures

(2)(e) Discharge, including aftercare. **The policy and procedure may not permit discharge of a recipient due to a return to use so long as the recipient reengages in treatment and complies with program policies and treatment protocol prospectively.**

COMMENT: We understand the intent behind a policy like this for a chronic, relapsing disorder. As written, it seems overly broad and difficult to apply to all treatment settings. There are some instances that a return to use also involves a breach of program policies and/or rules. What happens if an individual smuggles in contraband to a residential facility and uses an illicit substance? For outpatient, what type of timeframe is allowable before a possible discharge? What evidence does there need to be to demonstrate compliance with policies and protocols?

R 325.1363 **Service** ~~Treatment~~ plan~~s, excluding CAIT and SARF~~.

(1) Based upon the assessment~~s~~ made of a recipient's needs, a written ~~treatment~~ **service** plan**, which may include both medical and counseling services,** ~~shall~~ **must** be developed and recorded in the recipient's record. A ~~treatment~~ **service** plan ~~shall~~ **must** be developed **by a licensed or certified professional as referenced in these rules and** as promptly after the recipient's admission as feasible, ~~but before the recipient is engaged in therapeutic activities.~~ **but no later than either of the following**:

(a) The conclusion of the next session attended by the client for outpatient counseling programs.

(b) Twenty-four hours for methadone, residential, and residential withdrawal management programs.

(2) A service plan must include the recipient's signature agreeing to the plan and state when updates are made.

COMMENT – It is not possible to complete a comprehensive service plan within 24 hours of admission, especially for residential and residential withdrawal management programs. Often the full biopsychosocial assessment is not completed within 24 hours of admission to a withdrawal management program because the recipient is not capable of it. Also, proposed timeframes do not account for weekends or holidays. The only type

of Service Plan that could be produced within that timeframe would be pretty cookie cutter types of initial plans to comply with the standard, but not personalized or very comprehensive. This is unrealistic and providers will not be able to comply.

Additionally, to require this from an opioid treatment program within 24 hours of admission will cause delays in people receiving services. Programs will schedule individuals for their initial appointment with a physician often times without having a therapist available to conduct the assessment and complete a treatment plan the same day. Having an individual get started on his/her medication is a harm reduction strategy and is often utilized prior to a full biopsychosocial assessment being completed to not delay the admission.

R 325.1381 Outpatient counseling ~~services~~; program requirements.

(6) A licensee shall ensure that a limited certified counselor in not responsible for more than 32 recipients.

R 325.1383 Medication assisted treatment (MAT) services; Methadone program requirements.

(6) A licensee shall ensure that a limited certified counselor in not responsible for more than 32 recipients.

COMMENTS – (both 1381(6) and 1383 (6) – What information was used to determine that a limited certified counselor cannot be responsible for more than 32 recipients. The amount of services needed by each recipient is individualized. Additionally, organizations look at full time positions the same regardless of an individual's credentials. Limited certified counselors should not be forced to have a reduced case size, and should not be treated differently that those with a limited license. This standard puts a substantial burden on rural and frontier SUD providers in particular where the workforce is already a significant challenge.

R 325.1385 Residential program ~~services~~; requirements.

(5) A licensee shall ensure that a limited certified counselor is not responsible for more than 10 recipients.

(~~5~~**8**) A licensee shall provide and ensure recipient participation in ~~at least~~ **not less than** 15 hours per week of ~~treatment and~~ support ~~and rehabilitation~~ services **to meet the needs of the recipients** ~~to take place days, evenings, and weekends~~. **Not less than** ~~At least~~ ~~3~~**10** of the 15 hours must be ~~treatment~~ in the form of **treatment or rehabilitation evidence-based practice or services** ~~individual counseling, group counseling, social skills training, cognitive behavioral therapy, motivational interviewing, couples counseling, or family counseling for each recipient~~. Participation ~~shall~~ **must** be documented in the recipient record.

COMMENTS –
1385(5) COMMENTS – (6) – What information was used to determine that a limited certified counselor cannot be responsible for more than 32 recipients. The amount of services needed by each recipient is individualized. Additionally, organizations look at full time positions the same regardless of an individual's credentials. Limited certified

counselors should not be forced to have a reduced case size, and should not be treated differently that those with a limited license. This standard puts a substantial burden on rural and frontier SUD providers in particular where the workforce is already a significant challenge.

1385(8) It is risky for LARA to be setting one standard to cover the multiple levels of residential treatment programs that are recognized by federal experts like ASAM and CARF. For example, the hours per week requirement goes above what is required by the American Society of Addiction Medicine for ASAM Residential Level III.1 and what is required by the MDHHS. However, it is well below the requirements of 40 hours of support and treatment for ASAM Residential Level III.5 as required by MDHHS.

R 325.1388 Residential Withdrawal management program requirements.

(2) A program offering clinically managed withdrawal management services offers peer and social support services only and not offer or administer schedule II-V controlled substances for the management of withdrawal, including methadone and buprenorphine.

(4) A residential withdrawal management program shall meet all of the following requirements:

(c) A physician, physician's assistant, or advanced practice registered nurse shall review and assess each recipient upon admission and every 72 hours after the initial review and assessment to determine if the recipient is suitable for the services being offered. If a recipient is referred from a licensed acute care hospital, psychiatric unit, or hospital directly to a licensed residential withdrawal management program, the transfer documentation, including the health assessment from the transferring hospital, may be used as the initial assessment for admission if all of the following are met:

(6) A residential withdrawal management program offering medically monitored withdrawal management services must also meet both of the following requirements:

(a) A licensee shall have a physician, physician's assistant, or advanced practice registered nurse complete and document the medical and drug history, as well as a physical examination of the recipient, before administering any medications. In addition, any modification to medications or course of treatment must be documented in the recipient record and ordered by a physician, physician's assistant, or advanced practice registered nurse.

COMMENT:

1388(2) - Why are clinically managed withdrawal management programs not allowed to utilize medications that are allowed to be prescribed by primary care offices? Would a program be in violation of this standard if the program staff were supervising the self-administration of prescribed medications and that trained staff are taking medication according to prescription and legal requirements as defined with the State of Michigan's Medicaid Manual as well as the national standards of ASAM and CARF?

1388(4)(c) - Requiring a physician, physician's assistant, or advanced practice registered nurse to review and assess each recipient upon admission is exceeding the level of medical care required by the American Society of Addiction Medicine for this level of care. Well run withdrawal management programs have the recipient seen by these providers within 24 hours of admission after being evaluated by their trained designee. As stated in the ASAM Criteria, a physician (or physician extender) should be "available to assess the patient within 24 hours of admission." ASAM Criteria states, a registered nurse or other licensed and credentialed nurse is available to conduct a nursing assessment on admission. This requirement forces providers to limit admissions to those hours a physician or mid-level is available which impacts access to services and is not a national requirement. Individuals scheduled for admission into this level of care rarely arrive at their scheduled appointment time. Providers do not turn someone away who misses his/her appointment, but typically do not have physicians and/or mid-levels available to complete an initial assessment at the time of admission which could be 24 hours per day.

1388(6)(a) Requiring physical examinations prior to administering any medication exceeds the level of medical care necessary for this level of treatment. As stated in ASAM Criteria, a physician (or physician extender) should be "available to assess the patient within 24 hours of admission." ASAM Criteria states, a registered nurse or other licensed and credentialed nurse is available to conduct a nursing assessment on admission. This requirement forces providers to limit admissions to those hours a physician or mid-level is available which impacts access to services and is not a national requirement. Individuals scheduled for admission into this level of care rarely arrive at their scheduled appointment time. Providers do not turn someone away who misses his/her appointment, but typically do not have physicians and/or mid-levels available to complete an initial assessment at the time of admission which could be 24 hours per day.

R 325.1393 ~~Treatment~~ **Service** plan; specific recipient rights.

(3) Unless notified in writing before admission, a recipient may utilize medications as prescribed by a physician.

COMMENTS – This language is overly broad and creates a liability to the provider. It does not distinguish between medications that may have been prescribed by a physician through that program or if it is reference medications from a recipient's primary care physician. A provider is not always made aware of prescribed medications at the time of admission if the individual does not present with the medication or indicate all prescribed medications in the outpatient level of care, especially medication assisted treatment. Additionally, medications can be prescribed after admitted to a program. The proposed language would restrict a program from safely managing care.

Again, we appreciate many of the changes that LARA has proposed making to the Administrative Rules in this second phase of revision. The changes proposed could assist SUD provider to expand to help our State in its continued efforts to combat the opioid epidemic. The

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changes that we have suggested do not jeopardize the health and safety of individuals receiving SUD services. The changes will further improve access to the system of care, promote responsible development of the SUD workforce and are consistent with the ASAM Patient Placement Criteria, the Michigan Medicaid Manual and the policies of the Michigan Department of Health and Human Serivces. If LARA is willing to make some additional changes to its proposed draft, Michigan will have a set of rules that will be relevant for many years to come.

Again, thank you for the work that you have done on revising the rules and your consideration of the feedback received by the many stakeholders throughout the state.

Sincerely,

Sam Price

Sam Price, MA
SUD Board Chair, The Provider Alliance
President/CEO, Ten16 Recovery Network

Provider Alliance SUD Members:

- Addiction Treatment Services
- Arbor Circle
- Bear River Health
- CARE of Southeast Michigan
- Catholic Charities
- Easterseals Michigan
- Great Lakes Recovery Network
- Harbor Hall
- Hegira Health
- Hope Network
- Odyssey Village
- Ottagan Addiction Recovery (OAR)
- Pine Rest
- Sacred Heart
- Ten16 Recovery Network
- The Recovery Center; CEI Mental Health Authority
- The Phoenix House

TEN16 recovery network
Live free Be well Belong

Larry Horvath, Bureau of Community and Health Systems
Department of Licensing and Regulatory Affairs
Lansing, MI

Dear Larry,
I appreciate the long work that your team has been putting into getting the new Administrative Rules finalized. I also appreciate your willingness to take the feedback from providers in the field to inform your decisions.

There are a few final comments that Ten16 would share for the Department's consideration:

R 325.1301 Definitions.

(u) "Limited certified counselor" means an individual who is employed or who volunteers to work providing counseling to recipients in a substance use disorder services program licensed by the department under part 62 of the public health code, MCL 333.6230 to 333.6251, and who has completed a minimum set of state-approved requirements before completing the necessary prerequisites to become a certified alcohol and drug counselor by an organization approved or recognized by the department.

COMMENT – (u) It will be critical to understand what the state-approved requirements would be and how soon an individual would be able to earn that limited status. It will be a challenge going forward employing people in this status while they are working toward their limited credential because we may not have a means to be reimbursed for services. While I understand the need to eliminate the abuses that unscrupulous providers by manipulating the Development Plan, I think the unintended consequence of this hurts rural and frontier providers who don't have a large talent pool of licensed professionals. Additionally, it hurts the career path for those with lived experience to contribute to the field by blocking the ways that providers can use their skills while supervising their professional development

R 325.1363 **Service** ~~Treatment~~ plan~~s, excluding CAIT and SARF~~.

(1) Based upon the assessment~~s~~ made of a recipient's needs, a written ~~treatment~~ **service** plan**, which may include both medical and counseling services,** ~~shall~~ **must** be developed and recorded in the recipient's record. A ~~treatment~~ **service** plan ~~shall~~ **must** be developed **by a licensed or certified professional as referenced in these rules and** as promptly after the recipient's admission as feasible,~~ but before the recipient is engaged in therapeutic activities.~~ **but no later than either of the following**:

(b) Twenty-four hours for…..residential…programs.

COMMENT – It is not possible to complete a comprehensive service plan within 24 hours of admission, especially for residential treatment programs. Often because of the recipient's condition, a full biopsychosocial assessment may be difficult to complete within 24 hours of admission to these programs. The result of a standard like this will result in a basic, cookie cutter initial plan to satisfy the regulation and then a more personalized, comprehensive service plan. The PIHPs have a 72 hour standard to complete the Service Plan. While it can be a challenge even then, it is more realistic. Also, the proposed timeframes for all three programs being required to meet the 24 hour standard do not account for weekends or holidays.

R 325.1381 Outpatient counseling ~~services~~; program requirements.

(6) A licensee shall ensure that a limited certified counselor in not responsible for more than 32 recipients.

R 325.1383 Medication assisted treatment (MAT) services; Methadone program requirements.

(6) A licensee shall ensure that a limited certified counselor in not responsible for more than 32 recipients.

COMMENT – (both 1381(6) and 1383 (6) – Limited certified counselors should not be forced to have a reduced case size, and should not be treated differently that those with a limited license. This standard puts a substantial burden on rural and frontier SUD providers in particular where the workforce is already a significant challenge.

R 325.1385 Residential program ~~services~~; requirements.

(~~5~~**8**) A licensee shall provide and ensure recipient participation in ~~at least~~ **not less than** 15 hours per week of ~~treatment and~~ support ~~and rehabilitation~~ services **to meet the needs of the recipients** ~~to take place days, evenings, and weekends~~. **Not less than** ~~At least~~ ~~3~~**10** of the 15 hours must be ~~treatment~~ in the form of **treatment or rehabilitation evidence-based practice or services** ~~individual counseling, group counseling, social skills training, cognitive behavioral therapy, motivational interviewing, couples counseling, or family counseling for each recipient~~. Participation ~~shall~~ **must** be documented in the recipient record.

COMMENTS – It is risky for LARA to be setting one standard to cover the multiple levels of residential treatment programs that are recognized by federal experts like ASAM and CARF. For example, the hours per week requirement goes above what is required by the American Society of Addiction Medicine for ASAM Residential Level III.1 and what is required by the MDHHS. However, it is well below the requirements of 40 hours of support and treatment for ASAM Residential Level III.5 as required by MDHHS.

R 325.1388 Residential Withdrawal management program requirements.

(2) A program offering clinically managed withdrawal management services offers peer and social support services only and not offer or administer schedule II-V controlled substances for the management of withdrawal, including methadone and buprenorphine.

COMMENT - Why are clinically managed withdrawal management programs not allowed to utilize medications that are allowed to be prescribed by primary care offices? Would a program be in violation of this standard if the program staff were supervising the self-administration of prescribed medications and that trained staff are taking medication according to prescription and legal requirements as defined with the State of Michigan's Medicaid Manual as well as the national standards of ASAM and CARF?

If LARA is willing to accept the "supervision of self-administration" for medications that are prescribed and dispensed to a recipient, then the current language makes sense. But it is critical to understand how the language will be interpreted and applied.

(4) A residential withdrawal management program shall meet all of the following requirements:

(c) A physician, physician's assistant, or advanced practice registered nurse shall review and assess each recipient upon admission and every 72 hours after the initial review and assessment to determine if the recipient is suitable for the services being offered. If a recipient is referred from a licensed acute care hospital, psychiatric unit, or hospital directly to a licensed residential withdrawal management program, the transfer documentation, including the health assessment from the transferring hospital, may be used as the initial assessment for admission if all of the following are met:

COMMENT - Requiring a physician, physician's assistant, or advanced practice registered nurse to review and assess each recipient upon admission is exceeding the level of medical care required by the American Society of Addiction Medicine for this level of care. Well run withdrawal management programs have the recipient seen by these providers within 24 hours of admission after being evaluated by their trained designee. As stated in the ASAM Criteria, a physician (or physician extender) should be "available to assess the patient within 24 hours of admission." ASAM Criteria states, a registered nurse or other licensed and credentialed nurse is available to conduct a nursing assessment on admission. This requirement forces providers to limit admissions to those hours a physician or mid-level is available which impacts access to services and is not a national requirement. Individuals scheduled for admission into this level of care rarely arrive at their scheduled appointment time. Providers do not turn someone away who misses his/her appointment, but typically do not have physicians and/or mid-levels available to complete an initial assessment at the time of admission which could be 24 hours per day.

Again, thank you for the work that you have done on revising the rules and your consideration of the feedback received by the many stakeholders throughout the state.

Sincerely,

Samuel D Price, MA
President/CEO

Great Lakes Recovery Centers
Behavioral Health Services

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Ishpeming, MI 49849
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Toll Free: 1-855-906-GLRC
www.greatlakesrecovery.org

Date: August 30, 2022

Larry Horvath, Director
Bureau of Community and Health Systems
MI Department of Licensing and Regulatory Affairs
611 West Ottawa Street
P.O. Box 30664
Lansing, MI 48909

Dear Mr. Horvath:

On behalf of Great Lakes Recovery Centers, please accept these written comments as part of the public testimony on the proposed changes to the Administrative/Licensing Rules for Substance Use Disorder Services Programs, Phase II.

Great Lakes Recovery Centers is a nationally accredited long-standing provider of SUD residential treatment, detox, and outpatient services in many of the most rural communities across the State of Michigan, representing the Upper Peninsula.

I would like to begin by saying thank you to you and your staff for the time and consideration that has went into the process of evaluating the standards. You were willing to meet with us and made the time to better understand the impact that Phase I of the rule set changes had on services in the State. You have listened to provider needs over the past two years and we appreciate the ability to work with LARA on the crafting of meaningful SUD standards.

With the current proposed rule set, we have the following items for consideration:

Item #1: Brach Office Distance

R 325.1304 Application for branch office or mobile unit; requirements; review process; approval.

Item 1. 4.d The branch office is located within 75 miles from the parent location.

We would like for additional consideration with increasing the allowable mileage to 100 miles for extreme rural or frontier communities, especially those seen the Upper Peninsula and Norther Lower Michigan. We have offices that can be more than 75 miles apart that are limited use and operate as a branch or satellite location. These offices are sometimes the only source of support for people needing access to care.

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Item #2: Residential Withdrawal Management:

R 325.1388 Residential withdrawal management program requirements.

R325.1388(2). **(2) A program offering clinically managed withdrawal management services shall offer peer and social support services only and not offer or administer schedule II-V controlled substances, as classified under 21 USC 812, for the management of withdrawal, including methadone and buprenorphine.**

We are seeking the rescinding of R325.1388(2), or, **a defined interpretation** for programs that offer clinically managed residential withdrawal programming, (i.e. Social Detox), that the use of self-administered medications be allowed. We would like direction from LARA that the interpretation and enforcement of the language around controlled substances would allow programs to supervise an individual self-administering medication including controlled substances used to manage withdrawal symptoms. This is with the understanding that the medications are labeled, dispensed prescriptions in bottles with the individual's name on them from an independent pharmacy.

This practice would be in line state and federal program standards for Clinically Managed Withdrawal Management (ASAM Level 3.2) which all allow for the supervision of a person taking of their own prescribed medication in this level of programming. This includes:

- MDHHS/Michigan Medicaid Program Standards, Treatment Policy 13, p.6
- American Society for Addiction Medicine (ASAM), p.43
- U.S. Substance Abuse Mental Health Service Administration (SAMHSA), Detoxification and Substance Abuse Treatment, Treatment Improvement Protocol #45
- Carf (Commision on Accreditation of Rehabilitation Facilities) 2022 Behavioral Health Standards Manual, Section 2.e.2
-

This interpretation and application of R325.1388(2), to allow the supervision of self-administration, would be critical to allow for individuals who are directly transferred from a licensed acute care, psychiatric unit, or hospital as referenced in R325.1388(4). Many of these individuals may leave that facility with prescribed medications to manage their symptoms. These medications would be labelled and dispensed by an independent pharmacy.

Additionally, there is a contradictory statement in Part 5: Recipient Rights, that states the following:

(3) Unless notified in writing before admission, a recipient may utilize medications as prescribed by a physician.

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Item 3: Service Plan Timeline

R 325.1363 Service ~~Treatment~~ plan~~s, excluding CAIT and SARF~~.

Rule 1363. (1) Based upon the assessment~~s~~ made of a recipient's needs, a written ~~treatment~~ service plan, which may include both medical and counseling services, ~~shall~~ must be developed and recorded in the recipient's record. A ~~treatment~~ service plan ~~shall~~ must be developed by a licensed or certified professional as referenced in these rules and as promptly after the recipient's admission as feasible~~, but before the recipient is engaged in therapeutic activities.~~ but no later than either of the following:

(b) Twenty-four hours for methadone, residential, and residential withdrawal management programs.

In reference to the development of service plans within 24 hours for residential and residential withdrawal management programs, the nature of a comprehensive service plan being developed within 24 hours presents operational challenges for programs. Within treatment programs, the ability to compete a comprehensive bio-psycho-social assessment is a key component in the development of a well-crafted service plan. The time it takes to process this information with the client that results in (1) comprehensive service plan often requires more time that 24 hours. The suggested time interval is that the service plan would be completed within 48-62 hours.

Item 4: Limited Certified Counselor

(t) "Limited certified counselor" means an individual who is employed or who volunteers to work providing counseling to recipients in a substance use disorder services program licensed by the department under part 62 of the public health code, MCL 333.6230 to 333.6251, and who has completed a minimum set of state-approved requirements before completing the necessary prerequisites to become a certified alcohol and drug counselor by an organization approved or recognized by the department.

Outpatient: A licensee shall ensure that a limited certified counselor is not responsible for more than 32 recipients.

Residential: A licensee shall ensure that a limited certified counselor is not responsible for more than 10 recipients.

With respect to counselor capacities in Outpatient and Residential Services, the revised, more limiting, case load distinctions are a bit concerning. With reductions to the Substance Use Disorder counselor field, given restrictions imposed by the Michigan Certification Board for Addiction Professionals (MCBAP), based on interpterion of LARA intentions, will reduce the number of potential

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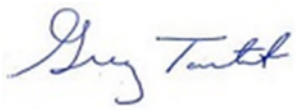
applicants for certification. The mis-interpretation of applying licensed mental health credentialing requirements to Substance Use Disorder professionals, is resulting in fewer eligible counselors. With fewer counselors available, the reduction of case load sizes will have a detrimental impact to treatment providers.

We would like to see no change in distinction with case load sizes for limited certified counselors compared to other limited licensed professionals listed in the rule set. It would appear to be a discriminatory distinction, as both sets of limited licensed/certified staff receive required clinical supervision.

Thank you in advance for your time and in reviewing this information and for consideration of the items outlined. I can be reached via phone at (906) 228-9694, or via email at: gtoutant@greatlakesrecovery.org

Respectfully submitted,



Greg Toutant, CEO

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August 30, 2022

Michigan Department of Licensing and Regulatory Affairs
Bureau of Community and Health Systems
Attn: Tammy Bagby
PO Box 30664
Lansing, MI 48909

RE: Proposed changes to administrative rules for Substance Use Disorder Service Programs, R 325.1301 - R 325.1399

On behalf of the Vital Strategies Overdose Prevention Program, we write to express our support for the Department of Licensing and Regulatory Affairs ("LARA"), Bureau of Community and Health Systems' ("Bureau") proposal to revise its regulations governing Substance Use Disorder Service Programs in Michigan. Vital Strategies is a global public health organization working with governments and communities in over 70 countries to help reduce preventable deaths, bringing expertise and technical assistance on issues like cardiovascular health, road safety, tobacco control, food policy, and drug overdose. Our organization is the lead partner in the Bloomberg Overdose Prevention Initiative, and we have been engaged intensively in the state of Michigan since early 2019. We look forward to continuing work with state, tribal, and local governments, providers, and community organizations in the coming years to support an equitable and sustainable reduction in overdoses in Michigan.

Amidst the COVID-19 pandemic, the country's drug overdose crisis has reached tragic new heights. The latest data from the Centers for Disease Control and Prevention ("CDC") show that overdose deaths in the United States continue to rise and, for the first time ever, surpassed 100,000 deaths in a single year.[1] Michigan saw a more than 24% increase in overdose deaths from 2019 to 2021, which was largely driven by opioids.[2,3] Treatment for opioid use disorder (OUD) with agonist medications buprenorphine and methadone[4] is most effective at reducing overdose and serious opioid-related acute care relative to other treatments, such as naltrexone or inpatient detoxification or residential services.[5] Agonist medications for OUD are associated with an estimated mortality reduction of 50% among people with OUD,[6] supporting the conclusion of the National Academies of Sciences, Engineering, and

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[1] Ahmad FB, Cisewski JA, Rossen LM, Sutton P. Provisional drug overdose death counts. National Center for Health Statistics. 2022. Designed by LM Rossen, A Lipphardt, FB Ahmad, JM Keralis, and Y Chong: National Center for Health Statistics.

[2] Number of Drug Poisoning/Overdose Deaths - Selected year(s). MiTracking. Michigan Department of Health and Human Services. https://mitracking.state.mi.us/?bookmark=238. Accessed August 26, 2022.

[3] Michigan Overdose Data to Action Dashboard. Michigan.gov website. https://www.michigan.gov/opioids/category-data. Accessed August 26, 2022.

[4] Also referred to throughout as "MOUD," meaning medications for opioid use disorder. MOUD is synonymous with medication assisted treatment, or "MAT."

[5] Wakeman SE, Larochelle MR, Ameli O, et al. Comparative Effectiveness of Different Treatment Pathways for Opioid Use Disorder. JAMA Netw Open. 2020;3(2):e1920622.

[6] Sordo L, Barrio G, Bravo MJ, et al. Mortality risk during and after opioid substitution treatment: Systematic review and meta-analysis of Cohort studies. BMJ. 2017.

Medicine in 2019 that "[t]he verdict is clear: effective agonist medication used for an indefinite period of time is the safest option for treating OUD."[7]

LARA's proposed changes to the administrative rules for Substance Use Disorder Service Programs would expand and enhance critical, life-saving access to agonist medications among Michiganders with OUD. Vital Strategies submits this comment to outline its support for key changes in the draft rules and offer several recommendations on how the rules can be further clarified or strengthened.

I. Key improvements in the proposed rules

a. Eliminating licensure barriers for prescribers of buprenorphine and facilitating access for recipients

Widespread access to the agonist medication buprenorphine is an essential overdose prevention and health promotion strategy. Providers who prescribe buprenorphine for OUD are already subject to unique federal requirements that have been identified as a barrier to addressing the enormous unmet need for evidence-based OUD treatment.[8,9,10,11] It is imperative that states not impose additional regulatory barriers that may further discourage providers from offering this life-saving medication to people with OUD.

Vital Strategies applauds the proposed elimination of Rule 325.1303(3)(c) and of related provisions that currently impose an additional licensure requirement under certain circumstances for buprenorphine prescribing to treat OUD. Moreover, Proposed Rule 325.1331(2)(c) requires that applicants and licensees maintain policies and procedures that include "referrals, including access to medication-

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[7] National Academies of Sciences, Engineering, and Medicine. Medications for opioid use disorder save lives. (Leshner AI, Mancher M, eds.). Washington, DC: The National Academies Press; 2019.

[8] The Drug Addiction Treatment Act of 2000 (DATA 2000) and its implementing regulations require practitioners to receive a separate registration (commonly referred to as an X waiver) prior to prescribing buprenorphine for the treatment of opioid use disorder. 21 USC § 823(g)(2). Only certain types of practitioners are eligible to receive an X waiver and must meet specified certification or training requirements. 21 USC § 823(g)(2)(G)(ii)-(iv). Practitioners must attest to their capacity to provide, directly or by referral, appropriate counseling and other appropriate ancillary services. 21 USC § 823(g)(2)(B)(ii)(II). Additionally, providers are restricted in the number of patients they may treat with buprenorphine at any given time, 21 USC § 823(g)(2)(B)(iii), with further requirements related to practice setting and ancillary services for practitioners with higher patient limits. *See* 42 CFR § 8.610-.655. Practice guidelines issued by the Department of Health and Human Services in April 2021 removed some, but not all, of these barriers for practitioners treating no more than 30 patients for OUD using buprenorphine, and all practitioners are still required to obtain an X waiver prior to prescribing buprenorphine for OUD. 86 Fed. Reg. 22439.

[9] Haffajee RL, Bohnert ASB, Lagisetty PA. Policy Pathways to Address Provider Workforce Barriers to Buprenorphine Treatment. American Journal of Preventive Medicine. 2018;54(6):S230-S242.

[10] Fiscella K, Wakeman SE, Beletsky L. Buprenorphine Deregulation and Mainstreaming Treatment for Opioid Use Disorder. JAMA Psychiatry. 2019;76(3):229. doi:10.1001/jamapsychiatry.2018.3685

[11] Oesterle TS, Thusius NJ, Rummans TA, Gold MS. Medication-assisted treatment for opioid-use disorder. Mayo Clinic Proceedings. 2019;94(10):2072-2086. "[I]t is estimated that only 11% of patients with an opioid use disorder are prescribed Food and Drug Administration (FDA)-approved medications for the disorder."

assisted treatment" and that "[t]he policy and procedure must facilitate access to medication-assisted treatment if desired by the recipient." Proposed Rule 325.1359(1)(a) similarly requires that a licensee include MOUD as a component of its assessment regarding support services if medication is not offered on site. This patient-centered approach will help ensure that those who desire it are connected with evidence-based medication treatment, even when seeking care from programs that do not offer this treatment modality directly.

b. Authorizing and/or clarifying operation of branch and mobile units to reach underserved communities and promoting diverse service models

In a recent survey conducted by LARA and Vital Strategies of more than 600 Michigan providers, approximately 41% of participants indicated that the addition of a satellite office or mobile unit to their practice could facilitate increased buprenorphine prescribing.[12] In the context of insufficient treatment capacity more broadly, challenges to agonist medication access may be even more pronounced in rural areas due to geographic, transportation, and financial barriers.[13] A 2018 study found that among Michigan counties that lacked MOUD treatment services, nearly all counties were concentrated in the state's northern and primarily rural areas.[14]

Proposed Rule 325.1304, which would authorize and/or clarify the operation of branch and mobile units in the state, is an important step toward increased MOUD access in rural and underserved areas in Michigan.

c. Promoting naloxone access

Naloxone, a medication which can rapidly reverse an opioid overdose and prevent death, should be widely accessible to communities, particularly people who use drugs and their networks. In 2017, only the state of Arizona had sufficient naloxone kits available to achieve a target of naloxone use in 80% of witnessed overdoses.[15] In the state of Michigan, just over half of Michigan pharmacies offer naloxone

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[12] Lyle V. Buprenorphine Prescribing Practices, Barriers & Facilitators: Survey Summary Report. (Cohen S, ed.). Michigan Department of Licensing and Regulatory Affairs (LARA) and Vital Strategies; 2022:28. Accessed August 26, 2022. https://www.michigan.gov/lara/-/media/Project/Websites/lara/communications/Buprenorphine-Prescribing-Practices-Survey-Summary-2022.pdf.

[13] Sigmon SC. Access to Treatment for Opioid Dependence in Rural America: Challenges and Future Directions. JAMA Psychiatry. 2014;71(4):359–360.

[14] Bohnert A, Erb-Downward J, Ivacko T. Opioid Addiction: Meeting the Need for Treatment in Michigan. Poverty Solutions University of Michigan; 2019. Accessed August 26, 2022. https://poverty.umich.edu/files/2019/05/PovertySolutions-OpioidTreatment-PolicyBrief-r4.pdf.

[15] Irvine MA, Oller D, Boggis J, Bishop B, Coombs D, Wheeler E, Doe-Simkins M, Walley AY, Marshall BDL, Bratberg J, Green TC. Estimating naloxone need in the USA across fentanyl, heroin, and prescription opioid epidemics: a modelling study. Lancet Public Health. 2022 Mar;7(3):e210-e218

without requiring a patient-specific prescription, despite a statewide standing order. Notably, areas with higher overdose fatality rates had fewer pharmacies offering naloxone via the standing order.[16]

Proposed Rule 325.1331(2)(f) would require programs to offer naloxone kits to "recipients with a history of opioid use or who are otherwise determined to be at risk for overdose." Establishing provision of naloxone to people at risk of overdose as a standard of care among licensed programs will better meet the needs of Michiganders, and importantly gets the overdose antidote directly into the hands of those at risk.

d. Aligning state standards for methadone treatment with federal law

Methadone, although highly effective as treatment for OUD, is constrained by a restrictive federal regulatory scheme. For example, federal regulations stipulate requirements for patient admission, frequency of drug testing, and allowance of take-home medication.[17] Michigan's current regulations for methadone programs exceed these already-restrictive federal standards around provision of care, particularly with respect to drug testing frequency[18] and permitted take-home doses.[19]

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[16] Dahlem CH, Myers M, Goldstick J, et al. Factors associated with naloxone availability and dispensing through Michigan's pharmacy standing order. The American Journal of Drug and Alcohol Abuse. 2022:1-10.

[17] See 42 CFR §§ 8.12(e), 8.12(f)(6), 8.12(i)(2)-(3).

[18] Michigan's current regulations require licensees to conduct random biweekly drug testing until a recipient has maintained biweekly drug-free results for a period of six months, after which a licensee must continue random monthly testing (a minimum of 18 drugs tests in the first year of treatment). Mich. Admin. Code r. 325.1383(14)(b)-(c). A recipient with a positive drug test must undergo weekly testing until the licensee documents three consecutive weekly drug-free results. Mich. Admin. Code r. 325.1383(14)(d). This contrasts with federal regulations, which require only eight random drug tests per year, with no requirement for additional drug tests based on a positive result. 42 CFR § 8.12(f)(6).

[19] This table compares the time-in-treatment requirements for take-home dosages under current Michigan regulations, Mich. Admin. Code r. 325.1383(15)(b), and federal regulations, 42 CFR § 8.12(i)(3). Note the significant departure of Michigan regulations from the federal standard starting at Day 271 of treatment.

Time in Treatment	*Michigan*	*Federal*
1-90 Days	1 Dose/week	1 Dose/week
91-180 Days	2 Doses/week	2 Doses/week
181-270 Days	3 Doses/week	3 Doses/week
271-365 Days	3 Doses/week	6-day supply
366-730 Days	4 Doses/week	2-week supply
731-1,095 Days	5 Doses/week	One-month supply
1,096-1,825 Days	6 Doses/week	One-month supply
1,826+ Days	2, 13 Doses/month	One-month supply

The table does not account for flexibilities in take-home doses authorized by the Substance Abuse and Mental Health Service Administration (SAMHSA) during the COVID-19 pandemic, which SAMHSA has announced will be extended and made permanent. *See* Methadone Take-Home Flexibilities Extension Guidance. Substance Abuse and Mental Health Services Administration (SAMHSA) website. https://www.samhsa.gov/medication-assisted-treatment/statutes-regulations-guidelines/methadone-guidance. Last Updated March 3, 2022. Accessed August 26, 2022.

The agency's proposed rules more closely align Michigan's requirements for Opioid Treatment Programs with federal law (i.e., standards regarding frequency of drug testing and take-home medication).[20] The proposed changes would make provision of methadone in the state lower barrier and easier for patients to access and remain in care.

e. Discouraging recipient discharge solely for return to use

Return to use, also commonly referred to as "relapse," is a common reason for providers to discharge patients from buprenorphine treatment. The 2022 survey summary report from LARA and Vital Strategies describes how "the most common reason for terminating [buprenorphine] treatment was a positive drug screen for illicit drug use."[21] The National Institute on Drug Abuse defines addiction as "a chronic, *relapsing* disorder."[22] Furthermore, in a sample derived from a nationally representative database, nearly 6 in 10 people with OUD had polysubstance use.[23] Effective, evidence-based treatment should employ compassionate, patient-centered responses to the combination of return to use as a normal feature of the recovery process, as well as the high prevalence of polysubstance use among people with OUD.

Under LARA's proposed rules, a licensee's policies and procedures "may not allow discharge of a recipient due to a return to use as long as the recipient reengages in treatment and complies with program policies and treatment protocol prospectively."[24] Vital Strategies commends this provision of the proposed rules and its intent to discourage termination of treatment solely on the basis of a patient's return to use.

II. Recommendations to further clarify or strengthen the proposed rules

a. Clarify and strengthen requirements regarding return to use and recipient discharge; consider the addition of similar protections on counseling

The language in proposed Rule 325.1331(2)(e) is ambiguous and Vital Strategies recommends that it be clarified and strengthened. Under the proposed language of this rule, it is unclear whether a licensee must have an affirmative prohibition in its policies and procedures of recipient discharge for return to use. An alternative interpretation of this proposed rule would be that it simply proscribes a discharge

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[20] Proposed Rule 325.1383(12) and strike of Rules 325.1383(14) and (15).

[21] Lyle V. Buprenorphine Prescribing Practices, Barriers & Facilitators: Survey Summary Report. (Cohen S, ed.). Michigan Department of Licensing and Regulatory Affairs (LARA) and Vital Strategies; 2022:33. Accessed August 26, 2022. https://www.michigan.gov/lara/-/media/Project/Websites/lara/communications/Buprenorphine-Prescribing-Practices-Survey-Summary-2022.pdf.

[22] National Institute on Drug Abuse. Drug Misuse and Addiction. National Institute on Drug Abuse. Published July 2020. https://nida.nih.gov/publications/drugs-brains-behavior-science-addiction/drug-misuse-addiction. (emphasis added).

[23] Hassan AN, Le Foll B. Polydrug use disorders in individuals with opioid use disorder. Drug Alcohol Depend. 2019 May 1;198:28-33.

[24] Proposed Rule 325.1331(2)(e).

policy that explicitly provides for recipient discharge based on return to use. The former reading is more protective of recipients and more likely to be adhered to by licensees. Additionally, the requirement of the proposed rule that a recipient prospectively comply with program policies and treatment protocol to be shielded from discharge based on return to use should be eliminated or, in the alternative, made more flexible and protective.

Vital Strategies recommends proposed Rule 325.1331(2)(e) be revised to read:

> "*This policy and procedure must prohibit discharge of a recipient due to a return to use*."

Barring that, the proposed provision should at minimum be changed to:

> "*This policy and procedure must prohibit discharge of a recipient due to a return to use as long as the recipient reengages in treatment and makes a good-faith effort to comply with program policies and treatment protocol prospectively.*"

Finally, Vital Strategies encourages the agency to consider the addition of a similar provision targeting discharge in response to a recipient declining counseling services. This could be accomplished with the following language:

> "*This policy and procedure must prohibit discharge of a recipient due to the recipient declining counseling services.*"

Behavioral health interventions like counseling can be an important adjunct to the use of medications like buprenorphine but are not necessary for treatment efficacy.[25,26,27] The American Society of Addiction Medicine ("ASAM") recommends in its National Practice Guidelines that a patient's decision to decline behavioral health treatment should not impede their access to medication treatment for OUD.[28]

b. Ensure that the requirements for branch offices and mobile units promote expanded access to care and are not too restrictive

While the proposed rules critically enable the operation of branch offices and mobile units, Vital Strategies recommends that the agency reexamine some of the limitations it proposes for these service modalities. Specifically, proposed Rule 325.1304 imposes the following constraints:

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[25] Wakeman SE, Larochelle MR, Ameli O, et al. Comparative Effectiveness of Different Treatment Pathways for Opioid Use Disorder. JAMA Netw Open. 2020;3(2):e1920622.
[26] California Health Care Foundation (CHCF). Buprenorphine: An Overview for Clinicians; 2019:8. Accessed August 30, 2022. https://www.chcf.org/wp-content/uploads/2019/08/BuprenorphineOverviewClinicians.pdf.
[27] Larochelle MR, Bernson D, Land T, et al. Medication for opioid use disorder after nonfatal opioid overdose and association with mortality: A cohort study. Annals of Internal Medicine. 2018 Aug; 169(3):137.
[28] American Society of Addiction Medicine. The ASAM National Practice Guideline for the Treatment of Opioid Use Disorder: 2020 Focused Update. 2020:37; Accessed August 30, 2022. https://www.asam.org/quality-care/clinical-guidelines/national-practice-guideline (" A patient's decision to decline psychosocial treatment or the absence of available psychosocial treatment should not preclude or delay pharmacological treatment of opioid use disorder, with appropriate medication management.")

- Branch offices may be open to recipients no more than 20 hours per week
- Branch offices must be located within 75 miles from the parent location
- The total number of branch offices may not exceed 3 locations for the parent organization
- The total number of mobile units may not exceed 3 for the parent organization

These limitations will undermine the reach and impact of branch offices and mobile units in Michigan, particularly given the state's size and the rurality of many of its regions. Vital Strategies advises that these limitations be eliminated or eased to maximize access to underserved areas of the state. For example, short of eliminating the limitations entirely, the rules could: authorize full-time (40 hours/week) operation of branch offices; increase geographic range of branch offices or at least enable exceptions to the 75-mile requirement with a written statement of need; increase the number of authorized branch offices and/or mobile units or, at minimum, enable exceptions upon written justification. The number, location, and operating parameters of branch offices and mobile units could also alternatively be included on a parent organization's application for licensure.

c. Limit the ability of licensees to force a recipient's discontinuation of appropriately prescribed medication

Proposed Rule 325.1393(3) provides that "[u]nless notified in writing before admission, a recipient may utilize medications as prescribed by a physician." Vital Strategies recommends elimination of this proposed provision because is suggests that the rules are permissive of a licensee forcing a recipient to discontinue use of appropriately prescribed medication. Instead, the rules should require licensees to allow recipients to continue use of prescribed medications unless clinically contraindicated.

Vital Strategies applauds the agency's proposed rule and its intent to expand and enhance critical SUD treatment services throughout the state. We encourage LARA to consider our comment and suggestions for improving the proposed rule. Should you have any questions, please do not hesitate to contact jrwan@vitalstrategies.org.

Sincerely,

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Ascension

August 30, 2022

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RE: Proposed Rule Set 2021-90 LR Substance Use Disorder Service Programs

Via Email: Lara-bchs-training@michigan.gov

Dear Ms. Bagby:

Thank you for the opportunity to provide comments on the proposed changes to the Substance Use Disorder Service Programs Rule Set, 2021-90 LR. Ascension Michigan supports many of the proposed revisions to the rules, however we have identified concerns which are outlined below.

Positive proposed changes to the rule set identified:
The draft rules include important changes that will improve access and quality of care for people with SUD in Michigan.

- Eliminating barriers to buprenorphine—the draft rules would eliminate the additional state licensure requirement related to the provision of buprenorphine. This change removes a potential barrier to expanded care across the state (e.g., proposed strike of Rule 325.1303(3)(c)). The proposed rules also require licensees to facilitate access to MOUD if desired by a recipient (proposed Rule 325.1331(2)(c)).
- Authorization of mobile and branch units—the draft rules authorize branch and mobile units, which will help increase access to care in underserved areas of the state (proposed Rule 325.1304).
- Promoting naloxone access—the proposed rules require programs to offer naloxone kits to recipients at high risk of overdose, a key overdose prevention strategy (proposed Rule 325.1331(2)(f)).
- Aligning methadone standards with federal law—the proposed rules more closely align Michigan's requirements for Opioid Treatment Programs with federal law (i.e., around frequency of drug testing and requirements for takehomes) (proposed Rule 325.1383(12) and strike of Rules 325.1383(14) and (15)).

- Discouraging discharge solely for return to use- under the proposed rules, a licensee's policies and procedures may not allow a person's discharge from a program due to a return to use as long as the person reengages in treatment and complies with program requirements (proposed 325.1331(2)(e)).

Concerns with proposed changes to the rule set identified:
The regulations identified below are either not easily feasible or will have unintended adverse consequences.

R 325.1331 (2)(e) - *Discharge, including aftercare. This policy and procedure may not allow discharge of a recipient due to a return to use as long as the recipient reengages in treatment and complies with program policies and treatment protocol prospectively.*

We have concerns that the rule does not make a distinction between outpatient services and residential services. When looking at the policy from the outpatient perspective, the policy does appear clear and easily applicable for patients receiving care under outpatient services. However, there is a dual mandate in residential treatment services that requires that individual patients are receiving treatment, including ensuring a "safe treatment environment" for other patients at the same time. The concern is that if a patient brings illicit substances into a residential treatment facility, it affects other patients and has great potential to create an unsafe healing environment.

Some of the most unsafe conditions identified in residential settings such as medically managed detoxification , inpatient rehabilitation services and halfway house services, occur when there are illicit substances brought in against policy rules which allows for uncontrolled use occurring with one or more patients. This return to use in a residential setting is detrimental for patients' treatment and can also regress SUD treatment progress for other individuals (either return to use, overdose, or intense distraction from treatment). The rule as proposed focuses on the individual but increases risk factors for the group at large receiving treatment, which may lead to violations of providing a safe treatment environment for other individuals receiving treatment.

Possible solutions include making a distinction between outpatient and inpatient services (i.e. the statement as written applies well to outpatient services) or acknowledging that major safety policy violations that impact other patients in a residential setting may be a cause for discharge (this can be integrated with R 325.1393 (4)). As written, the policy may have material safety impacts.

We propose including either a written statement that clearly identifies making a distinction between outpatient and inpatient services (i.e. the rule section applies to outpatient services as well) or include language that major safety policy violations, that impact other patients in a residential setting, may be a cause for discharge.

R 325.1363 (1)(b) - Rule 1363. (1) - ***Based upon the assessment made of a recipient's needs, a written service plan, which may include both medical and counseling services, must be developed and recorded in the recipient's record. A service plan must be developed by a licensed or certified professional as referenced in these rules and as promptly after the recipient's admission as feasible, but no later than either of the following: (a) The conclusion of the next session attended by the client for outpatient counseling programs. (b) Twenty-four hours for methadone, residential, and residential withdrawal management programs.***

We view this rule does not adequately account for the condition of most patients admitted to a medically monitored residential withdrawal unit. In most cases, the condition in the first 24 hours is intoxication. For Ascension Brighton Center for Recovery, we find this is up to a breathalyzer of 0.300, and in various stages of objectively measured withdrawal. A patient cannot be "cleared" psychiatrically for suicidal thinking until they are at 0.000 on a breathalyzer. Under the proposed, the rule is mandating the creation of detailed service plans with patients in various forms of intoxication which is neither medically nor legally appropriate. We strongly urge considerations regarding cognitive dysfunction and withdrawal, to defer major portions of service plan decision making, including medication management planning, therapy style, family session planning, etc. until the patient is clinically out of the intoxication and moderate withdrawal phase. We propose a breathalyzer count of 0.000, a Clinical Opiate Withdrawal Scale (COWS) score of < 12 and a Clinical Institute Withdrawal Assessment (CIWA) score of < 8. Making detailed service plans prior to this level of medical stability is harmful to the patient and will lend to the need for undue adjustments to the plan of care, and could be coercive.

We propose including language exempting the specific level of care of medically managed residential withdrawal from this 24 hour rule where these types of situations are the most likely to occur. The rule can be applied to the other treatment settings in the proposed rules without the same level of risk of coercion (methadone, residential services without withdrawal management, and other outpatient services).

R 325.1388 (6)(a) - ***A residential withdrawal management program offering medically monitored withdrawal management services must also meet both of the following requirements: (a) A licensee shall have a physician, physician's assistant, or advanced practice registered nurse complete and document the medical and drug history, as well as a physical examination of the recipient, before administering any medications. In addition, any modification to medications or course of treatment must be documented in the recipient record and ordered by a physician, physician's assistant, or advanced practice registered nurse.***

This rule has a major barrier to access to care. In most acute hospital settings, a full history and physical examination can be deferred for late afternoon and evening admissions until the following day (24 hours). If a patient is admitted late in the day to a medically monitored

withdrawal management program and cannot start needed medications such as buprenorphine, lorazepam, phenobarbital or other withdrawal medications, this is a major safety concern.

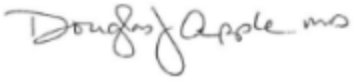
Withdrawal management using standardized medication protocols and scoring as previously mentioned (CIWA, COWS, etc.) is a well documented approach to the care of a patient in withdrawal in a safe manner. This proposed rule does not allow for nurse assessment which includes: physical examination; point of care testing like breathalyzers, COVID-19, urine drug screens; medical review including current medication, medication allergies, and history of complicated withdrawal symptoms. This nursing assessment along with board certified Addiction Medicine physician review is enough information to safely start highly standardized withdrawal management protocols safely and effectively.

Although unintended, the proposed rule without modification would likely have adverse effects including the reduction of access to care by restricting the allowed admissions for only certain hours due to physician / Advanced Practice Providers availability and/or creating significant safety issues by denying patients' access to medication management for withdrawal symptoms and thereby increasing Against Medical Advice (AMA) discharges and safety related events (seizures, delirium tremens, severe avoidable withdrawal morbidity, etc.).

We propose including language to allow for nurse triage and assessment with physician oversight of the admissions process to increase access to care and lower the rates of complicated withdrawal to improve patient safety. We also urge the consideration to clarify in the rule set that there may be a window of 24 hours to complete the initial history and physical examination and that the initial history and physical examination should not hinder access to generally recognized medication-assisted treatment for withdrawal management.

Please contact me at (586) 753-1120 or douglas.apple@ascension.org if you have any questions regarding these comments or if you need additional information.

Sincerely,



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Chief Clinical Officer, Ascension Michigan

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A Chapter of American Society of Addiction Medicine

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August 31, 2022

Tammy Bagby
Department of Licensing and Regulatory Affairs
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Ottawa Building
611 W. Ottawa St
Lansing, MI 48909

Re: Comments on Rule Set 2021-90 LR, Administrative Rules for Substance Use Disorder Service Programs

Dear Ms. Bagby,

On behalf of the Michigan Society of Addiction Medicine (MISAM), the medical specialty society representing physicians and clinicians in Michigan who specialize in the prevention, treatment, and recovery from addiction, thank you for the opportunity to comment on this important topic. As the addiction and overdose epidemic continues to significantly impact our state, your efforts to support providers and ensure that individuals with substance use disorder (SUD) receive evidence-based treatments are greatly appreciated.

On the whole, we strongly support the changes proposed in Rule Set 2021-90 LR, or the Administrative Rules for Substance Use Disorder Service Programs. We believe that this rule set will benefit patients and addiction providers and help expand access to care to patients at a time of desperate need. In particular, we fully support the change to decrease barriers to buprenorphine treatment and support clinicians to increase treatment access. Other changes to enhance access to naloxone, authorize mobile treatment units, align drug testing standards with federal requirements, and strengthen program retention also stand out as significant improvements. We commend you for addressing these important issues. We also appreciate the important efforts to balance the need to increase treatment while also working to promote high quality care.

However, we have a few areas of potential concern and propose slight adjustments:

R 325.1363 (1)(b), pertains to the timely development of recipient treatment service plans. The proposed rule requires the development of a treatment service plan "as promptly after the recipient's admission as feasible, but before the recipient is engaged in therapeutic activities." While we understand the need to develop treatment plans as soon as possible, we are concerned that the inclusion of residential withdrawal management programs in this 24-hour treatment service plan requirement could impact their ability to provide stabilizing care. Especially when patients are experiencing acute symptoms of withdrawal, development of detailed treatment plans beyond medically safe detoxification could be challenging**. In turn, we suggest that you consider exempting residential withdrawal management program from this 24-hour treatment service plan rule or provide some more flexibility in terms of timeline.**

Further, **R 325.1388 (6)** requires that qualified personnel complete and document a recipient's medical and drug use history before administering any medication. We are concerned about the implications of this rule for immediate access to care, specifically in hospital and withdrawal management settings. In these fast-paced settings, qualified personnel must be empowered to exercise their best medical judgement to respond quickly and decisively. **To prevent creating barriers to immediate medication for addiction treatment (MAT) for withdrawal management, we urge that you add flexibility for situations when patients may need urgent medication treatment.** This might be done by either allowing for nurse triage and assessment with physician oversight or allow some window of time (e.g. 24 hrs) to complete the initial history and physical examination

Finally R 325.1331 (2)(e) concerns discharge policies, including aftercare. Specifically, this policy discourages discharge of a recipient due to a return to use as long as the recipient willingly reengages in treatment and complies with program policies and treatment protocol. We fully agree with the intent of this rule. However, as written, the proposal does not distinguish between outpatient settings and more intensive residential inpatient settings. Some residential programs may have difficulty following this rule due to wanting to balance safety and treatment needs of other patients. **As such, we request that you add a distinction between outpatient and residential settings to this rule, specifying that discharge based solely on return to use is undesirable in residential facilities but may need to be balanced with the promotion of a safe treatment environment for other participants of the program.**

MISAM is grateful to have been incuded as a collaborator throughout this process. We feel that the proposed rule set is a substantial step forward. And we hope to continue our engagement as it nears full implementation. Please do not hesitate to contact me at polandc2@msu.edu if there is any future support our organization can provide.

Sincerely,

Timothy Gammons, DO, FASAM
President, Michigan Society of Addiction Medicine

Cara A. Poland, MD, MEd, DFASAM
Advocacy Chair, Michigan Society of Addiction Medicine

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continuum of care

August 31, 2022

Bureau of Community and Health Systems
Attention: Tammy Bagby
P.O. Box 30664
Lansing, MI 48909
Lara-bchs-training@michigan.gov

Dear Ms. Bagby:

Thank you for the opportunity to provide feedback on the Department of Licensing and Regulatory Affairs proposed changes to the Substance Use Disorder Service Programs rule set.

Sacred Heart appreciates LARA making further updates to the rule set based on feedback dating back to 2018 and also feedback on drafts released within the past year. I am submitting feedback on behalf of Sacred Heart Rehabilitation Center, Inc from the review of the draft rule set dated June 23, 2022. Sacred Heart has been providing substance use disorder (SUD) services in Michigan since 1967. We are the largest SUD treatment provider for publicly funded adults in the state. We provide the full continuum of care at more than ten locations in Michigan. Sacred Heart is more than willing to participate in conversations regarding the feedback we provided, or as subject experts on future reviews of the rule set.

The following feedback is based on the latest draft released:

R 325.1301 Definitions.
(t) “Limited certified counselor” means an individual who is employed or who volunteers to work providing counseling to recipients in a substance use disorder services program licensed by the department under part 62 of the public health code, MCL 333.6230 to 333.6251, and who has completed a minimum set of state-approved requirements before completing the necessary prerequisites to become a certified alcohol and drug counselor by an organization approved or recognized by the department.

COMMENT – (u) What are the state approved requirements?

R 325.1301 Definitions.
(w) “Methadone program” means a program engaged in opioid treatment of an individual with an opioid agonist treatment medication registered under 21 USC 823(g)(1), methadone.

COMMENT - (w) Suggest referring to a program as an Opioid Treatment Program. This is the national recognition for a program that provides methadone. A provider cannot utilize methadone without obtaining federal certification called Opioid Treatment Program. Referringo a program as a “Methadone Program” is archaic and contributes to unnecessary stigma associated with the term methadone.

R 325.1309 Waiver from licensure survey.
Rule 1309. (1) The department shall provide and make publicly available a procedure for when a licensee may be eligible for a waiver from a licensure survey. The procedure must include maintaining a list of approved accrediting bodies for programs.
(2) On or before October 1 of each year, the department shall publish a list of programs to receive a licensure survey in the next calendar year.
(3) An eligible licensee may request a waiver from licensure survey on or before November 1 of each year. A waiver request shall be submitted on a form authorized by the department.
(4) On or before January 1 of the survey year, the department shall provide in writing an approval or denial of the waiver from licensure survey to the licensee.

COMMENTS – Does this exist? I do not see it listed on draft dated June 23, 2022.

R 325.1363 **Service** ~~Treatment~~ plan~~s, excluding CAIT and SARF~~.
Rule 1363. (1) Based upon the assessment~~s~~ made of a recipient's needs, a written ~~treatment~~ **service** plan**, which may include both medical and counseling services,** ~~shall~~ **must** be developed and recorded in the recipient's record. A ~~treatment~~ **service** plan ~~shall~~ **must** be developed **by a licensed or certified professional as referenced in these rules and** as promptly after the recipient's admission as feasible, ~~but before the recipient is engaged in therapeutic activities.~~ **but no later than either of the following**:

(a) The conclusion of the next session attended by the client for outpatient counseling programs.

(b) Twenty-four hours for methadone, residential, and residential withdrawal management programs.

(2) A service plan must include the recipient's signature agreeing to the plan and state when updates are made.

COMMENT – It is not possible to have a completed service plan done within 24 hours of admission, especially for residential and residential withdrawal management programs. Often the full biopsychosocial assessment is not completed within 24 hours of admission to a withdrawal management program. Also, proposed timeframes do not account for weekends or holidays. This is unrealistic and providers will not be able to comply. Additionally, to require this from an opioid treatment program within 24 hours of admission will cause delays in people receiving services. Programs will schedule individuals for their initial appointment with a physician often times without having a therapist available to conduct the assessment and complete a treatment plan the same day. Having an individual get started on his/her medication is a harm reduction strategy and is often utilized prior to a full biopsychosocial assessment being completed to not delay the admission.

~~R 325.1377 Community change, alternatives, information, and training (CAIT).~~ **Rescinded.**
~~R 325.1379 Screening and assessment, referral, follow-up (SARF) services; requirements.~~ **Rescinded.**

COMMENT – Agree with eliminating these sections

R 325.1381 Outpatient counseling~~services~~; program requirements.
Rule 1381.
(6) A licensee shall ensure that a limited certified counselor in not responsible for more than 32 recipients.

COMMENTS – (6) – What information was used to determine that a limited certified counselor cannot be responsible for more than 32 recipients. The amount of services needed by each recipient is individualized. Additionally, organizations look at full time positions the same regardless of an individual's credentials. Limited certified counselors should not be forced to have a reduced case size.

R 325.1383 Medication assisted treatment (MAT) services; Methadone program requirements.
(6) A licensee shall ensure that a limited certified counselor in not responsible for more than 32 recipients.
(12) A licensee shall **comply with all requirements set forth in 42 CFR § 8.**

(6) What information was used to determine that a limited certified counselor cannot be responsible for more than 32 recipients? The number of services needed by each recipient is individualized and different. Additionally, organizations look at full time positions the same regardless of an individual's credentials. Limited certified counselors should not be forced to have a reduced case size.

(12) Support this change

R 325.1385 Residential program ~~services~~; requirements.
(5) A licensee shall ensure that a limited certified counselor is not responsible for more than 10 recipients.
(~~5~~**8**) A licensee shall provide and ensure recipient participation in ~~at least~~ **not less than** 15 hours per week of ~~treatment and~~ support ~~and rehabilitation~~ services **to meet the needs of the recipients** ~~to take place days, evenings, and weekends~~. **Not less than** ~~At least~~ ~~3~~**10** of the 15 hours must be ~~treatment~~ in the form of **treatment or rehabilitation evidence-based practice or services** ~~individual counseling, group counseling, social skills training, cognitive behavioral therapy, motivational interviewing, couples counseling, or family counseling for each recipient~~. Participation ~~shall~~ **must** be documented in the recipient record.

COMMENTS –
(5) What information was used to determine that a limited certified counselor cannot be responsible for more than 10 recipients. Additionally, organizations look at full time positions the same regardless of an individual's credentials. Limited certified counselors should not be forced to have a reduced case size.

(8) The hours per week requirement goes above what is required by the American Society of Addiction Medicine for ASAM Residential Level III.1 and what is required by the MDHHS.

R 325.1388 Residential Withdrawal management program requirements.
Rule 1388.
(2) A program offering clinically managed withdrawal management services offers peer and social support services only and not offer or administer schedule II-V controlled substances for the management of withdrawal, including methadone and buprenorphine.
(4) A residential withdrawal management program shall meet all of the following requirements:
(c) A physician, physician's assistant, or advanced practice registered nurse shall review and assess each recipient upon admission and every 72 hours after the initial review and assessment to determine if the recipient is suitable for the services being offered. If a recipient is referred from a licensed acute care hospital, psychiatric unit, or hospital directly to a licensed residential withdrawal management program, the transfer documentation, including the health assessment from the transferring hospital, may be used as the initial assessment for admission if all of the following are met:
(6) A residential withdrawal management program offering medically monitored withdrawal management services must also meet both of the following requirements:
(a) A licensee shall have a physician, physician's assistant, or advanced practice registered nurse complete and document the medical and drug history, as well as a physical examination of the recipient, before administering any medications. In addition, any modification to medications or course of treatment must be documented in the recipient record and ordered by a physician, physician's assistant, or advanced practice registered nurse.

COMMENTS - (2) Why are clinically managed withdrawal management programs not allowed to utilize medications that are allowed to be prescribed by primary care offices?

(4)(c) Requiring a physician, physician's assistant, or advanced practice registered nurse to review and assess each recipient upon admission is exceeding the level of medical care required by the American Society of Addiction Medicine for this level of care. As stated in the ASAM Criteria, a physician (or physician extender) should be "available to assess the patient within 24 hours of admission." ASAM Criteria states, a registered nurse or other licensed and credentialed nurse is available to conduct a nursing assessment on admission. This requirement forces providers to limit admissions to those hours a physician or mid-level is available which impacts access to services and is not a national requirement. Individuals scheduled for admission into this level of care rarely arrive at their scheduled appointment time. Providers do not turn someone away who misses his/her appointment, but typically do not have physicians and/or mid-levels available to complete an initial assessment at the time of admission which could be 24 hours per day.

6(a) Requiring physical examinations prior to administering any medication exceeds the level of medical care necessary for this level of treatment. As stated in ASAM Criteria, a physician (or physician extender) should be "available to assess the patient within 24 hours of admission." ASAM Criteria states, a registered nurse or other licensed and credentialed nurse is available to conduct a nursing assessment on admission. This requirement forces providers to limit admissions to those hours a physician or mid-level is available which impacts access to services and is not a national requirement. Individuals scheduled for admission into this level of care rarely arrive at their scheduled appointment time. Providers do not turn someone away who misses his/her appointment, but typically do not have physicians and/or mid-levels available to complete an initial assessment at the time of admission which could be 24 hours per day.

R 325.1391 Recipient rights.
R 325.1393 ~~Treatment~~ **Service** plan; specific recipient rights.
(3) Unless notified in writing before admission, a recipient may utilize medications as prescribed by a physician.

COMMENTS – This is a liability to the provider. A provider is not always made aware of prescribed medications at the time of admission if the individual does not present with the medication or indicate all prescribed medications in the outpatient level of care, especially medication assisted treatment. Additionally, medications can be prescribed after admitted to a program. The proposed language would restrict a program from safely managing care.

Again, thank you for the opportunity to provide feedback and for the changes that were previously made. Sacred Heart is supportive of the majority of the changes proposed by LARA. The feedback/concerns highlighted above promote the health and safety of individuals in our care, further improve the delivery of services within our system and create consistency between the licensing rules and the American Society of Addiction Medicine Patient Placement Criteria. I can be reached at 810-392-2167, Extension 1303, or electronically at pnelson@sacredheartcenter.com.

Sincerely,

Paula Nelson, President and CEO

Bagby, Tammy (LARA)

From: Kanzoni Asabigi <kasabigi@recovery4detroit.com>
Sent: Wednesday, August 31, 2022 12:52 PM
To: LARA-BCHS-Training
Subject: Proposed SUD Rule Changes - Rule Set 2021-90LR

Hello:
Thank you for allowing me to make a presentation at the hearing this morning. Below is a written summary of the feedback.
Positive Highlights:
• Eliminating barriers to buprenorphine—the draft rules would eliminate the additional state licensure
requirement related to the provision of buprenorphine. This change removes a potential barrier to expanded
care across the state (e.g., proposed strike of Rule 325.1303(3)(c)). The proposed rules also require licensees to
facilitate access to MOUD if desired by a recipient (proposed Rule 325.1331(2)(c)).
• Authorization of mobile and branch units—the draft rules authorize branch and mobile units, which will help
increase access to care in underserved areas of the state (proposed Rule 325.1304).
• Promoting naloxone access—the proposed rules require programs to offer naloxone kits to recipients at high
risk of overdose, a key overdose prevention strategy (proposed Rule 325.1331(2)(f)).
• Aligning methadone standards with federal law—the proposed rules more closely align Michigan's
requirements for Opioid Treatment Programs with federal law (i.e., around frequency of drug testing and

requirements for takehomes) (proposed Rule 325.1383(12) and strike of Rules 325.1383(14) and (15)).

• Discouraging discharge solely for return to use: under the proposed rules, a licensee's policies and procedures
may not allow a person's discharge from a program due to a return to use as long as the person reengages in
treatment and complies with program requirements (proposed 325.1331(2)(e)).

Thank you.

--
Kanzoni Asabigi, MD, PhD, MPH
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Bagby, Tammy (LARA)

From: Emmy Ellis <EEllis@arborcircle.org>
Sent: Wednesday, August 31, 2022 1:35 PM
To: LARA-BCHS-Training
Subject: Licensing rules - public comment

Hello,

Thank-you for the opportunity to offer public comment regarding the proposed changes to the SA licensing rules. Please accept my comments below for official public comment regarding the proposed changes to the Substance Use Disorder Service Programs rule set.

Regarding prevention:
While the content, model and structure of substance use disorder prevention programs could look to the outside as a low risk activity, the reality is that prevention programs and services across the State of Michigan are often interacting with our most vulnerable populations; children and youth. Prevention providers are going into schools, providing after-school programming, holding groups with youth at risk for a variety of concerns like homelessness, abuse and neglect, early use of alcohol and other drugs, mental illness and more. Prevention providers also provide services convening community members, educating parents, and many more activities. While it may seem like these are low risk activities with few safety concerns, removing the CAIT license completely would remove the requirements for agencies providing these services to ensure proper staff licensure, proper staff training, proper safety monitoring and safety practices, and could impact ethical practice. While an individual staff licensure could ensure individual ethical practice, licensing an organization ensures that all prevention practices have a minimum standard of excellence in caring for our most vulnerable.

Regarding Treatment:

- Under Part II R 325.1303, it is stated that a license is not required for an individual offering psychological medical or social services within the scope of his or her individual professional license and not under a group or organization offering substance use disorder services." Can you clarify if appropriately licensed clinicians can provide SUD treatment (other than methadone tx) in a private practice?
- Under Part 2 Subpart A, R 325.1304**,** the branch location hours are limiting at 20 hours. There are opportunities for clinicians to provide more than 20 hours at a separate location especially in more rural areas. However, the sites would never have the need for a fully licensed office. I would like you to consider increasing the hours from 20 to 32 hours in order to accommodate the needs in these communities.
- "Under Subpart D R 325.1363, completion of an individualized treatment plan at the next session is not always feasible. The newly State of MI required ASAM Continuum can take 2 sessions to complete. Additionally, people often need more time to fully engage. Recovery is a strain emotionally and physically, sharing this and translating it into a meaningful plan takes longer than one session. I would suggest 3 sessions or 30 days, whichever comes first.

Thank-you again for the opportunity to provide input.

Emmy Ellis LMSW
She/Her pronouns
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BHSH System

August 31, 2022

Tammy Bagby
Department of Licensing and Regulatory Affairs
Bureau of Community and Health Systems
PO Box 30664, Lansing, MI 48909

Via Electronic Submission

Re: Administrative Rules for Substance Use Disorder Service Programs Rule Set 2021-90 LR

Dear Ms. Bagby:

BHSH System appreciates the opportunity to provide comments on the Administrative Rules for Substance Use Disorder Service Programs Rule Set 2021-90 LR. Formed on February 1, 2022 from two leading health systems in Michigan (Beaumont Health and Spectrum Health), BHSH System is a not-for-profit health system that provides care and coverage with an exceptional team of 64,000+ dedicated team members—including more than 11,500 physicians and advanced practice providers and more than 15,000 nurses offering services in 22 hospitals, 300+ outpatient locations and several post-acute facilities—and Priority Health, a provider-sponsored health plan serving over 1.2 million members across the state of Michigan. We are boldly creating a future where health is simple, affordable, equitable and exceptional. It is from the perspective of an integrated health system that we offer the following comments.

As an organization we are committed to providing low barrier access to high quality substance use treatment. **Therefore, our substance use providers and our organization as a whole is in strong agreement with the proposed administrative changes.**

These proposed rule changes will help better differentiate the levels of care available at an outpatient buprenorphine and naltrexone office versus a methadone treatment program. Often patients who have more serve disease and need closer monitoring are followed by a methadone clinic. However, patients with less serve disease, or those further along in treatment may not need this level of strict monitoring. It may in fact be a hinderance to patients being able to continue in care. Therefore, by decreasing the number of urine drug screens required during one year, and by expanding and modifying rules related to outpatient buprenorphine and naltrexone clinics, we will be able to better care for our patients and improve access to treatment.

We also believe that the adoption of the proposed mobile health rules will allow our provider team to expand our reach to some of the highest risk and most underserved patients. The lessons learned from the COVID-19 pandemic have showed that the use of mobile health and telehealth are essential tools to provide equitable and quality substance use care to our rural communities. **With that said, BHSH System believes that if a parent organization has the staffing, resources, and community demand to provide more than three mobile units, then they should be allowed to do so.**

In addition, removing the x-waiver requirement is essential. The x-waiver requirement is a barrier that often times prevents pain medicine specialists or other medical providers from feeling comfortable prescribing buprenorphine. This is an unnecessary barrier that prevents patients from accessing a safe treatment option for chronic pain and prevents medical providers from providing MAT to patients with opioid use disorder.

We also strongly support of the proposed changes to expand to behavioral health support. **We are also in strong support of increasing the recipient-to-counselor ratio and allowing limited certified counselors to provider behavioral health support.** This proposed change will have an immediate improvement on access to behavioral health support for our patient population. **Implementing a similar model to Wisconsin's SUD 1 to 50 limited certified counselor-to-recipient ratio would be even more beneficial for the residents of Michigan.**

Overall, it is our view that the spirit of the proposed regulations supports the de-stigmatizing of substance use treatment and to minimize the risks of harm in those patients using substances. This is aligned with harm reduction and the best evidence-based approach to substance use treatment.

Thank you for your consideration of our comments,

Colleen Lane
Addiction Medical Director
Spectrum Health West Michigan

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THE SENATE
STATE OF MICHIGAN

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ENVIRONMENTAL QUALITY
TRANSPORTATION

August 31, 2022

Bureau of Community and Health Systems
Attn: Tammy Bagby
PO Box 30664,
Lansing, MI 48909

Bureau of Community and Health Systems:

The intent of this letter is to seek clarification on a current ruleset on the Substance Use Disorders Service Program. This information would benefit the JCAR Committee before it is submitted.

The rule states:

R 325.1388 Residential withdrawal management program requirements.
Rule 1388. (1) Residential withdrawal management programs must be based on a documented assessment of the recipient's needs and a subsequent agreement between the recipient and the provider about the services to be offered.
(2) A program offering clinically managed withdrawal management services shall offer peer and social support services only and not offer or administer schedule II-V controlled substances, as classified under 21 USC 812, for the management of withdrawal, including methadone and buprenorphine.
(3) A program offering medically monitored withdrawal management services shall offer medical and nursing care and may administer medications for the management of withdrawal.

We were contacted by the Provider Alliance, a trade association for SUD providers including some of our constituents. They are concerned about the language in R325.1388(2). It states “A program offering clinically managed withdrawal management services (*also known as social detox*) shall offer….and not offer or administer schedule II-V controlled substances, as classified under 21 USC 812, for the management of withdrawal, including methadone and buprenorphine….” (p. 22)

We are looking for assurance from LARA that the interpretation and enforcement of the language around controlled substances would allow programs to supervise an individual self-administering medication including controlled substances used to manage withdrawal symptoms. This is with the understanding that the medications are labeled, dispensed prescriptions in bottles with the individual’s name on them from an independent pharmacy.

This practice would be in line with state and federal program standards for Clinically Managed

Withdrawal Management (ASAM Level 3.2) which all allow for the supervision of a person taking of their own prescribed medication in this level of programming. This includes:

- MDHHS/Michigan Medicaid Program Standards, Treatment Policy 13, p.6 (LINK)
- American Society for Addiction Medicine (ASAM), p.43 (LINK)
- U.S. Substance Abuse Mental Health Service Administration (SAMHSA), Detoxification and Substance Abuse Treatment, Treatment Improvement Protocol #45 (LINK)
- Carf (Commision on Accreditation of Rehabilitation Facilities) 2022 Behavioral Health Standards Manual, Section 2.e.2

This interpretation and application of R325.1388(2), to allow the supervision of self-administration, would be critical to allow for individuals who are directly transferred from a licensed acute care, psychiatric unit, or hospital as referenced in R325.1388(4). Many of these individuals may leave that facility with prescribed medications to manage their symptoms. These medications would be labelled and dispensed by an independent pharmacy.

Thank you for taking the time to read this letter. In order for us to move forward in confidence with the JCAR process, we are requesting a written response clarifying how LARA would be interpreting, applying and enforcing this specific standard. This will inform the committee how it would need to act when the proposed ruleset comes to us. As you know if the legislature proposes that the rule be changed, the agency or department can either make the decision to change the rule, and within 30 days resubmit the rule to the committee or make the decision to not change the rule and notify the committee.

Sincerely,

Ed McBroom
State Senator
38th District

Bumstead
State Senator
34th District

Luke Meerman
State Representative
88th District

CC: “Katherine Wienczewski, Administrative Rules Manager, Michigan Office of Administrative Hearings and Rules”.