

Michigan Office of Administrative Hearings and Rules

Administrative Rules Division (ARD)

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**REGULATORY IMPACT STATEMENT
and COST-BENEFIT ANALYSIS (RIS)**

Agency Information:

Department name:

Licensing and Regulatory Affairs

Bureau name:

Bureau of Community and Health Systems

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Rule Set Information:

ARD assigned rule set number:

2021-90 LR

Title of proposed rule set:

Substance Use Disorder Service Programs

Comparison of Rule(s) to Federal/State/Association Standard

1. Compare the proposed rules to parallel federal rules or standards set by a state or national licensing agency or accreditation association, if any exist.

The regulation of substance use disorder (SUD) service programs is a state function. There are no direct federal rules or standards that states must follow. There are ancillary federal regulations administered by the Substance Abuse and Mental Health Services Administration (SAMHSA) in the U.S. Department of Health and Human Services that address reimbursement and funding, however, these responsibilities are handled by the Michigan Department of Health and Human Services (MDHHS). The new rules do not change this established system.

A. Are these rules required by state law or federal mandate?

Section 6234 of the Public Health Code, MCL 333.6234, permits the department to promulgate rules under the Administrative Procedures Act for the administration of Part 62. Substance Abuse Services of the Code and for the licensing of SUD services programs under Part 62.

B. If these rules exceed a federal standard, please identify the federal standard or citation, describe why it is necessary that the proposed rules exceed the federal standard or law, and specify the costs and benefits arising out of the deviation.

The regulation of SUD service programs is a state function. There are no specific federal standards pertaining to the regulation of these programs. Additionally, there are no changes to the relationship between federal and state on reimbursement and funding issues.

2. Compare the proposed rules to standards in similarly situated states, based on geographic location, topography, natural resources, commonalities, or economic similarities.

Branch offices

Michigan's current Substance Use Disorder (SUD) Administrative rules do not include branch offices. The proposed rules add regulations for branch offices which expand access to care. MI's branch office requirements are similar to Minnesota's requirements, but slightly more restrictive. Michigan's proposed rules require the branch offices to be associated with a parent location that has been licensed for a minimum of 2 years, be open to recipients no more than 20 hours per week, be located no more than 75 miles from the parent location, and not exceed 3 locations for the

parent organization. As many branch offices will be located in less populated areas, the branch offices will not function at full level.

In Minnesota, licensees are required to provide services at any of the licensee's licensed locations or at another suitable location such as a school, government building, medical or behavioral health facility, or social service organization. If services are provided offsite from the licensed site, the reason must be documented. Their regulations don't include clauses regarding the minimum or maximum number of hours staff can work and number of branch office locations per parent organization.

Mobile units

Michigan's current administrative rules do not include mobile units. Mobile units will expand access to treatment to areas in MI where access to SUD services is limited. Michigan's proposed mobile unit requirements are similar to Indiana, but slightly more restrictive as MI's rules require a mobile unit to be licensed under a parent location that has been licensed for a minimum of 2 years, return each night to the licensed location if the unit offers methadone treatment, and not exceed 3 mobile units for the parent organization.

In Indiana, SUD programs can supplement treatment infrastructure shortages by providing services in a mobile unit or temporary location including the following locations: geographically high-risk areas for SUD, medically underserved areas, areas with a high incidence of neonatal abstinence syndrome, areas with high forensic treatment service needs. IN's rules do not have provisions for the minimum number of years the parent location must be in operation and the maximum distance a mobile unit can travel beyond the parent location, thus rendering Indiana's rules slightly less restrictive than Michigan's proposed rules.

Naloxone access

Michigan's proposed rules require programs to offer a naloxone kit to all recipients with a history of opioid use or who are otherwise determined to be at risk for overdose. Indiana and Minnesota have regulations similar to Michigan.

In Indiana, the Senate Enrolled Act 406-2015, "Aaron's Law" passed to allow residents to obtain a prescription for naloxone if they believe someone they know is at risk of an opioid overdose.

In Minnesota, a person who is not a health care professional is authorized to possess or administer an opiate antagonist that is prescribed, dispensed, or distributed by a licensed health care professional.

Staff development and training

MI's proposed rules expand in-service education categories. In addition to the previous training categories, training must now include first aid, medical emergencies, risks associated with withdrawal management, naloxone administration, cultural competency, confidentiality, mandated reporting, individualized treatment, and recipient rights. Compared to Illinois, Michigan's required staff development and training is more comprehensive to ensure recipient safety and high-quality healthcare. Illinois' staff development and training requirements offer slightly more flexibility.

Illinois requires staff training, but the training categories are not as expansive. There an initial employee orientations must include an overview of organizational operations, bloodborne pathogens, and HIV and AIDS.

Prevention services (CAIT)

Michigan's proposed rules deregulate prevention services or CAIT (community change, alternatives, information and training).

In Ohio, prevention services are regulated by the Department of Mental Health and Addiction Services.

Screening and assessment, referral, follow-up (SARF)

Michigan's proposed rules deregulate SARF. Other states in the Great Lakes Region do not have rules analogous to SARF.

Limited certified counselor

Michigan's proposed rules add "limited certified counselor" to mean an individual who is employed by or volunteers to work providing counseling to recipients in a SUD program. These individuals have completed a minimum set of state-approved requirements prior to completing the necessary prerequisites to become a certified alcohol and drug counselor. These counselors may provide counseling as defined by the proposed rules. Similar to Michigan, WI has counselors-in-training with comparable rules.

In Wisconsin, SUD counselors-in-training may provide counseling services under the supervision of a clinical supervisor. WI's counselors-in-training have larger recipient-to-counselor ratios (50 recipients for every 1 counselor) than Michigan's recipient-to-counselor ratio in the proposed rules for the state's comparable limited certified counselor (32 recipients for every 1 counselor; this is roughly half the counselor-to-recipient ratio of a licensed or fully certified counselor). However, Wisconsin's rules exceed Michigan's proposed rules given counselors-in-training are required a minimum of 2 hours of supervision per every 40 hours worked and a minimum of one in person meeting every calendar month.

Outpatient counseling

Similar to Indiana and Wisconsin, Michigan's proposed rules regulate outpatient counseling. MI's proposed rules have expanded the types of counselors that can provide counseling services. While licensed, limited licensed, and certified counselors and psychologists can be responsible for no more than 65 recipients, limited certified counselors can now be responsible for no more than 32 recipients.

In Indiana, licensed psychologists, licensed clinical addiction counselors, and master's level licensed therapists can be included in addiction treatment teams. Unlike Michigan, Indiana includes recovery coaches certified by a credentialing body.

In Wisconsin, outpatient treatment services can be supplied by a counselor-in-training, substance abuse counselor, or clinical substance abuse counselor. Similar to Michigan's limited certified counselors, Wisconsin's professional counselors-in-training can provide outpatient counseling services. Wisconsin's recipient-to-counselor ratio for counselors-in-training is less restrictive than Michigan's ratio for limited certified counselors as Wisconsin's counselors-in-training can be responsible for no more than 50 recipients.

Medication Assisted Treatment

Compared to Indiana and Wisconsin, Michigan's proposed SUD rules are nearly identical in the regulation of methadone clinics. The Medication Assisted Treatment (MAT) services section of the current rules is being proposed to be removed and replaced with "Methadone program requirements." This change reflects the proposed deregulation of buprenorphine and naltrexone for opioid use disorder treatment. The proposed deregulation of buprenorphine and naltrexone treatment for opioid use disorder will simplify the licensure process for buprenorphine and naltrexone prescribers and facilitate increased access to these medications.

In Indiana, opioid treatment programs (OTPs) are regulated. Like Michigan, these regulations are particularly concerned with methadone.

In Minnesota, OTP regulations align with 42 CFR § 8.12. Identical to Michigan, Minnesota's rules for take-home medications and drug testing in OTPs adhere to federal minimum standards. On the other hand, Minnesota's rules for recipient-to-counselor ratios for OTPs differ from Michigan's proposed rules. These rules are more restrictive in

Minnesota than Michigan. In Minnesota, a counselor can have no more than 50 recipients. Alternatively, in Michigan, a licensed, limited licensed, or certified counselor can have no more than 65 recipients.

Residential program

Similar to Wisconsin, MI's proposed rules continue to regulate residential programs. Similar to the proposed rules for outpatient counseling, the proposed revisions to the residential program rules include expanding the types of counselors that can provide counseling services as required in recipient service plans. In a residential program, a licensed counselor or a certified counselor cannot be responsible for more than 20 recipients. Alternatively, the proposed rules state that limited certified counselors cannot be responsible for more than 10 recipients. At least 10 of the 15 hours of required support services must be in the form of treatment or rehabilitation evidence-based services.

In Wisconsin, transitional residential treatment services are regulated. The recipient-to-counselor ratio is more restrictive than Michigan as a program must have one full-time SUD counselor for every 15 recipients.

Withdrawal management/ detoxification

Michigan's proposed rules regulate clinically managed and medically monitored withdrawal management. This is mainly a renaming of the former residential detoxification program.

Similar to Michigan, IL, regulates clinically managed and medically monitored withdrawal management programs along with other American Society of Addiction Medicine (ASAM) withdrawal management criteria. MI's proposed rules are more restrictive as there are additional staff qualifications, required training, and procedures for clinically managed withdrawal management programs.

Inpatient services

MI's proposed rules deregulate inpatient SUD services. Inpatient SUD services are only available to licensed acute care hospitals, however the requirement of an additional SUD license to a higher level hospital license is redundant and unnecessary. Deregulation of this service would align with other regional states.

A. If the rules exceed standards in those states, please explain why and specify the costs and benefits arising out of the deviation.

Branch office

Michigan's proposed rules for branch offices exceed the standards in other states, such as Minnesota, given Michigan's proposed rules include provisions regarding the maximum number of branch offices, staff hours, and distance from a parent location. The addition of branch offices to the proposed rules will reduce costs to service providers while expanding access to SUD services. The proposed standards which limit the number, staffing, and distances of branch offices are important for recipient safety and can improve the practicality of regulatory enforcement activities.

Mobile units

Michigan's proposed rules for mobile units will expand access to SUD services. The limitations on the number of mobile units per parent location and the distances the mobile units can travel from parent locations exceed some of the standards of mobile units in similar states such as Indiana. These proposed regulations will safeguard recipient care and safety.

Staff training and development

The proposed staff training and development requirements exceed other states such as Illinois' staff training and development rules. However, the proposed staff training and development rules are essential to ensure SUD service staff are sufficiently trained and able to effectively respond to and provide care to a range of recipient populations.

Outpatient services

Michigan's outpatient counseling services are less restrictive than other states such as Indiana and Wisconsin on most provisions with the exception of limited certified counselors. The recipient-to-counselor ratio in Michigan is less restrictive and offers more flexibility than other states such as Wisconsin, but unlike Wisconsin, Michigan reduces the recipient-to-counselor ratio for limited certified counselors. The rules for limited certified counselors may limit care to some recipients but are in place to offer better recipient care and safety.

Withdrawal management/detoxification

Michigan's proposed rules also expanded the withdrawal management categories to align with the ASAM criteria more closely. While Illinois fully adheres to ASAM criteria, Michigan's proposed rules include additional staffing, training, and other criteria beyond the ASAM criteria. The additional staffing criteria may lead to additional costs in the salary for a physician, physician assistant, or advanced practice registered nurse conducting review, assessment, and referral procedures. All of the additional provisions are important for ensuring the proper health care and safety of recipients.

3. Identify any laws, rules, and other legal requirements that may duplicate, overlap, or conflict with the proposed rules.

The regulation of SUD services programs is a state function; there are no other laws, rules, or other legal requirements that duplicate, overlap, or conflict with the proposed rules. There are ancillary federal regulations administered by SAMHSA in the U.S. Department of Health and Human Services that address reimbursement and funding. , these responsibilities are handled by MDHHS. The new rules do not change this established system.

A. Explain how the rules have been coordinated, to the extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter. This section should include a discussion of the efforts undertaken by the agency to avoid or minimize duplication.

The coordination and interplay with other federal, state, and local laws remains the same and consistent in the proposed rules as with the existing rules. The proposed rules comport with, and do not duplicate or conflict with federal, ASAM or Drug Enforcement Agency (DEA) regulations.

4. If MCL 24.232(8) applies and the proposed rules are more stringent than the applicable federally mandated standard, provide a statement of specific facts that establish the clear and convincing need to adopt the more stringent rules.

The federal government has not mandated that the state promulgate SUD rules.

5. If MCL 24.232(9) applies and the proposed rules are more stringent than the applicable federal standard, provide either the Michigan statute that specifically authorizes the more stringent rules OR a statement of the specific facts that establish the clear and convincing need to adopt the more stringent rules.

Michigan's current administrative rules are more stringent than the federal standards. The proposed rules will align with 42 CFR § 8.12 - Federal opioid treatment standards, and the drug testing frequency and take-home medications, in particular, will no longer be more restrictive than the federal standards.

Purpose and Objectives of the Rule(s)

6. Identify the behavior and frequency of behavior that the proposed rules are designed to alter.

The SUD Administrative Rules currently provide for the regulation of licensed SUD service programs. The current rule set will be rescinded and provisions of those rules will be recodified and revised into a new rule set that will comport with today's standards of practice and eliminate unnecessary burdens by doing the following:

Recipient-to-counselor ratios

Incorporating and modifying, where necessary, the existing requirements. The proposed SUD Administrative Rules will expand and modernize the recipient-to-counselor ratios in facilities licensed as outpatient SUD programs, methadone programs, residential programs and withdrawal management programs which will permit programs to utilize limited certified counselors to provide counseling services to recipients.

Methadone treatment programs

For facilities with the medication assisted treatment services license, the requirement that facilities that prescribe buprenorphine or naltrexone to more than 100 individuals at one time be licensed has been removed. The rules have been replaced to only regulate methadone programs. These new rules also replaced the drug testing and take-home medication schedules and replaced them with the provision that licensees comply with all requirements set forth in 42 CFR. Programs will see a reduction in costs due to a decrease in the frequency of how often drug testing must be performed. The current rules require 18 drug tests during year one of treatment and 12 drug tests during year two. Through adhering to federal standards, maintenance methadone treatment will require 9 drug tests during year one and 8 drug tests during year two.

Staffing requirements

The proposed rules clarify staffing credentials and requirements. The proposed rules acknowledge and permit the use of limited certified counselors in all SUD license types, which greatly expands the pool of possible employees. The existing SUD Administrative Rules only permit licensed and certified counselors.

Terminology

The proposed SUD Administrative Rules update and expand the rules' terminology and licensed services to reflect today's care practices and recipient protections. Rules were proposed for licensed services that are not included in the current rules such as branch office, methadone program, mobile unit, and residential withdrawal management program. New terminology was also added such as evidence-based practice or services, licensed marriage and family therapist, and limited certified counselor.

SUD licensure regulatory categories have been streamlined to reduce redundancy and inconsistency in the requirements. This promotes an effective regulatory environment while providing the least burdensome approach for compliance to these regulations. There are currently approximately 900 licensed SUD programs in the State of Michigan. The current rules were last updated in 2018. The proposed rules will provide greater staffing flexibility to licensees, allowing for potentially lower costs.

A. Estimate the change in the frequency of the targeted behavior expected from the proposed rules.

The rules will be updated to reflect the current public health efforts that pertain to SUD service programs. Staffing requirements will be expanded to allow programs to include other licensed health professionals to meet staff requirements, such as limited certified counselors. The proposed rules established a recipient-to-counselor ratio for the expanded list of counselors who can provide counseling in SUD programs: limited certified counselors.

The rules for methadone programs have been updated to deregulate the provision of buprenorphine and naltrexone services. Methadone programs have also reduced the required frequency of drug testing from at least 18 drug tests during year one of treatment to 9 drug tests during year one. After completing the first year of treatment, the required annual drug tests reduced from 12 times per year to 8 times per year in accordance with the federal standards. The take-home medication allowances also increased to align with federal standards whereby the current rules allow for up to 2, 13 take-home doses in a month after five years of treatment. The proposed rules would allow for a maximum one-month supply of take-home medication after two years of continuous treatment.

The proposed rules added provisions for branch offices, mobile units, and residential withdrawal management programs. These additions will allow for greater flexibility in the types of care recipients can receive for SUD treatment. These additional licensed programs will also expand access to treatment. This is particularly true for mobile units and branch offices, which can reach locations in which there is an unmet treatment need.

The proposed rules emphasize the use of telemedicine in SUD service programs, in accordance with federal guidelines, the Act 218 of 1956, the Insurance Code of 1956, 1956 PA 218, MCL 500.100 to 500.8302.

B. Describe the difference between current behavior/practice and desired behavior/practice.

The current behavior places unnecessary limits on the types of professionals who can provide counseling services, the types of facilities in which people can receive treatment, and regulations pertaining to medication assisted treatment services. The new behavior and practice reflect the current practices used by other states and the industry as a whole, which should allow for more counselors to be available for an increasing population of at-risk clients and greater continuity of care for people receiving methadone treatment.

The inclusion of other counseling professionals such as limited certified counselors, will improve the recipient access to care from the current rules that limit the types of counseling professionals that can be listed as the required staff for a licensed program. This will change the behavior of licensed programs so that they can fully staff their programs with a larger selection of counselors

C. What is the desired outcome?

The current SUD Administrative Rules exclude limited certified counselors from providing counseling in SUD service programs, regulate facilities that provide buprenorphine and naltrexone to more than 100 recipients at a given time, restricts the take home medication allowance for medication assisted treatment recipients, required more drug tests per year than the federal requirements, and limited the settings in which people receive SUD treatment.

The proposed SUD Administrative Rules will expand the types of professionals that can provide counseling services and allow for drug testing frequencies, take home medication allowances, and a variety of settings where people can receive treatment that represent the current practice nationwide. The proposed deregulation of buprenorphine and naltrexone treatment will also expand access to these medications. This will directly help and relieve the needs state-wide for an increasing number of people in need of SUD treatment and care.

7. Identify the harm resulting from the behavior that the proposed rules are designed to alter and the likelihood that the harm will occur in the absence of the rule.

The existing SUD Administrative Rules do not sufficiently address the unmet treatment needs in geographic areas especially impacted by the overdose crisis. There are SUD services throughout the state; however, some people with SUD disorders have exorbitant travel times to reach evidence-based services.

The proposed SUD Administrative Rules will allow for licensed programs to offer greater individualized treatment options to people with SUD. The mobile units and branch offices will allow parent locations to expand the reach of their services to communities with unmet treatment needs. The addition of SUD service types such as clinically managed residential withdrawal management services will provide an additional individualized treatment option to Michigan residents with SUD. Greater access to SUD services will improve the safety and care of Michigan residents during the current overdose crisis.

A. What is the rationale for changing the rules instead of leaving them as currently written?

The existing rule set does not comport with today's standards of practice but still requires providers to comply with these requirements.

8. Describe how the proposed rules protect the health, safety, and welfare of Michigan citizens while promoting a regulatory environment in Michigan that is the least burdensome alternative for those required to comply.

The proposed rules protect the health, safety, and welfare of Michigan citizens by clarifying when a license is needed by those providing SUD services while at the same time reducing burdens on those required to be licensed. The proposed SUD Administrative Rules update the terminology and delivery model with today's care practices and recipient protections. Inclusions for health, safety, and welfare consist of expanding the staff development and training requirements, adding terminology regarding the provision of evidence-based services, and requiring facility protocol for offering naloxone kits. SUD licensure regulatory categories have been streamlined to reduce redundancy and inconsistency in the requirements, and undefined and unused categories have been eliminated from the administrative rules. This promotes an effective regulatory environment while providing the least burdensome approach for compliance to these regulations.

9. Describe any rules in the affected rule set that are obsolete or unnecessary and can be rescinded.

The existing SUD Administrative Rules have not been updated since 2018, so the proposed SUD rules rescind and recodify but maintain the required SUD oversight as required from the Public Act.

Rules that have been identified as obsolete or unnecessary include rules pertaining to SARF, prevention services, and inpatient services. These SUD categories were removed from the rule set as they lacked statutory authority, modernization and/or did not meet current industry standards.

Fiscal Impact on the Agency

Fiscal impact is an increase or decrease in expenditures from the current level of expenditures, i.e. hiring additional staff, higher contract costs, programming costs, changes in reimbursements rates, etc. over and above what is currently expended for that function. It does not include more intangible costs for benefits, such as opportunity costs, the value of time saved or lost, etc., unless those issues result in a measurable impact on expenditures.

10. Please provide the fiscal impact on the agency (an estimate of the cost of rule imposition or potential savings for the agency promulgating the rule).

There is no significant fiscal impact to the agency. Licensing is funded by fees and general funds. These rules are revenue neutral to the state agency. The addition of mobile units and branch offices to the administrative rules may result in an increase in new license requests and fees received, these will likely be offset from the deregulation of CAIT and SARF licensed facilities. This will likely lead to a neutral impact on the agency.

11. Describe whether or not an agency appropriation has been made or a funding source provided for any expenditures associated with the proposed rules.

There have been no appropriations made or a funding source provided that are associated with these rules. These rules are revenue neutral to the state agency.

12. Describe how the proposed rules are necessary and suitable to accomplish their purpose, in relationship to the burden(s) the rules place on individuals. Burdens may include fiscal or administrative burdens, or duplicative acts.

The proposed SUD Administrative Rules provide clarity for providers and recipients, ensure that SUD service programs comply with industry and licensing standards, and set forth minimum criteria for delivery of these services to protect residents. The proposed rules help to ensure that recipients and residents in Michigan who are seen by licensed health professionals and licensed counselors in a wide variety of physical settings are able to achieve consistent, repeatable, and standardized care that protects their safety and rights while receiving treatment. Any burdens or duplicative acts may stem from the licensure of a facility that also employs separately licensed individuals, but this burden is minimal to the overall benefits for recipients and citizens. Facility licensure containing licensed individuals is already used under the current SUD Administrative Rules, is used with other health facilities such as hospitals, nursing homes, and surgical facilities, and doesn't extend any burden or duplicity beyond the current practice. This regulatory process helps assure recipient care and safety is provided during the delivery of important and needed health care services.

A. Despite the identified burden(s), identify how the requirements in the rules are still needed and reasonable compared to the burdens.

There are no identified burdens.

Impact on Other State or Local Governmental Units

13. Estimate any increase or decrease in revenues to other state or local governmental units (i.e. cities, counties, school districts) as a result of the rule. Estimate the cost increases or reductions for other state or local governmental units (i.e. cities, counties, school districts) as a result of the rule. Include the cost of equipment, supplies, labor, and increased administrative costs in both the initial imposition of the rule and any ongoing monitoring.

There are no anticipated increases or decreases to revenue for other state or local governmental unit. The SUD licensure remains a voluntary, service-driven licensure, meaning those entities not providing treatment or care are not required to seek licensure. Government entities that provide SUD services are not required to obtain licensure from LARA. A reduction in cost is likely to be seen by many SUD licensees because of the addition of branch locations that can be licensed under the parent location, the reduction in the frequency of drug testing for methadone programs, and the addition of limited certified counselors that can be licensed to provide counseling services. These changes may result in lower cost for procedures and staffing.

14. Discuss any program, service, duty, or responsibility imposed upon any city, county, town, village, or school district by the rules.

There are no programs, services, duties, or responsibilities imposed on the entities named.

A. Describe any actions that governmental units must take to be in compliance with the rules. This section should include items such as record keeping and reporting requirements or changing operational practices.

There are no programs, services, duties or responsibilities imposed on the entities named.

15. Describe whether or not an appropriation to state or local governmental units has been made or a funding source provided for any additional expenditures associated with the proposed rules.

There is no appropriation to state or local government required.

Rural Impact

16. In general, what impact will the rules have on rural areas?

The proposed rules affect the State of Michigan as a whole by establishing statewide minimum standards for all SUD services program licensees. Research suggests a need for more SUD service providers in Michigan's rural areas. The revised regulations, such as the deregulation of buprenorphine services and the inclusion of clinically managed residential withdrawal management services, could foster an environment in which it is easier for these programs to function, in turn, expanding access to SUD services.

A. Describe the types of public or private interests in rural areas that will be affected by the rules.

These revised rules will ameliorate any unnecessary regulatory obstacles to establishing SUD programs throughout Michigan, but these changes will be especially impactful in rural areas.

Environmental Impact

17. Do the proposed rules have any impact on the environment? If yes, please explain.

The proposed rules do not have an impact on the environment.

Small Business Impact Statement

18. Describe whether and how the agency considered exempting small businesses from the proposed rules.

Article 6 of the Public Health Code (Act 368 of 1978) dictates who is required to be licensed when providing SUD services or programs in Michigan. The Public Act is not changing with the new SUD Administrative Rules and remain applicable to the same potential licensee as the existing rules. The scope of those required to be licensed remains the same, and the Public Act does not permit an exemption from licensure under the rules for any entity, including small businesses.

19. If small businesses are not exempt, describe (a) the manner in which the agency reduced the economic impact of the proposed rules on small businesses, including a detailed recitation of the efforts of the agency to comply with the mandate to reduce the disproportionate impact of the rules upon small businesses as described below (in accordance with MCL 24.240(1)(a-d)), or (b) the reasons such a reduction was not lawful or feasible.

Small businesses are not exempt, and reductions targeted specifically for small businesses were not lawful or feasible due to Article 6 of the Public Health Code (Act 368 of 1978) requiring SUD licensing for any entity offering SUD services.

The proposed SUD Administrative Rules will expand and modernize the types of counselors who can provide counseling in facilities licensed as an outpatient SUD program, which will permit programs to utilize counselors that require lower wages. For licensed methadone programs, the reduction in the frequency of required drug testing that must be performed per recipient annually will lower costs associated with drug testing. The current SUD administrative rules require 18 drug tests during the first year of treatment and 12 drug tests during the second year of treatment and beyond. The proposed rules will require 9 drug tests during the first year of treatment and 8 drug tests during the second year of treatment and beyond. This reduction in drug testing frequency directly aligns with federal standards.

The proposed rules will also acknowledge and permit the use of limited certified counselors in all SUD license types, which greatly expands the pool of possible employees and could lead to a reduction in employee costs with lower salary employees and greater job competition. The existing SUD Administrative Rules only permit licensed counselors and certified counselors, a smaller pool of employees at a higher average salary cost, so savings will likely be achieved on staffing costs.

The economic impact and cost reduction is applicable to all licensed SUD facilities and does not benefit or hinder small businesses over large businesses.

A. Identify and estimate the number of small businesses affected by the proposed rules and the probable effect on small businesses.

Since small businesses are not exempt from licensing and reductions targeted specifically for small businesses were not lawful or feasible due to Article 6 of the Public Health Code (Act 368 of 1978) requiring SUD licensing for any entity offering SUD services, all licensed SUD facilities will be affected by the rule. Approximately 900 facilities are licensed as SUD programs, ranging from large hospital chains with multiple site locations to small single licensed SUD operators. The probable effect for all businesses licensed as SUD is an opportunity to bring on board more staff due to the broadening of the range of facilities eligible to fulfill the provision of SUD services such as branch locations and mobile units. The expansion of counseling profession requirements in which limited certified counselors are included in the licensure can reduce costs by enabling lower cost employees to fulfill the counseling capacity.

B. Describe how the agency established differing compliance or reporting requirements or timetables for small businesses under the rules after projecting the required reporting, record-keeping, and other administrative costs.

The LARA BCHS State Licensing Section does not currently establish differing compliance or reporting requirements or timetables for small businesses under the existing rules. The proposed rules cannot and do not make a new distinction under statute for small businesses, so the proposed rules do not establish differing compliance and reporting requirements or timetables for small businesses.

C. Describe how the agency consolidated or simplified the compliance and reporting requirements for small businesses and identify the skills necessary to comply with the reporting requirements.

The changes being made are administrative and do not affect the reporting requirements.

D. Describe how the agency established performance standards to replace design or operation standards required by the proposed rules.

There are no design or operation standards in the proposed rules.

20. Identify any disproportionate impact the proposed rules may have on small businesses because of their size or geographic location.

The proposed rules have no disproportionate impact on small businesses because of their size or geographic location.

21. Identify the nature of any report and the estimated cost of its preparation by small businesses required to comply with the proposed rules.

There are no reports required for small businesses.

22. Analyze the costs of compliance for all small businesses affected by the proposed rules, including costs of equipment, supplies, labor, and increased administrative costs.

There are no unique costs of compliance for small businesses. The costs for all businesses that are required to achieve SUD licensing will be reduced due to the expansion of the types of counselors (limited certified counselors) that can be staffed in licensed facilities. Employees with less experience but with limited certification can now be employed at SUD facilities, which will bring a reduction in employee cost due to the wage difference between other professional counselors and a limited certified counselor.

The SUD rules include a protocol to offer a naloxone kit to all recipients with a history of opioid use disorder. This may increase supply costs for SUD programs. Other than offering naloxone kits, there are no equipment requirement changes or changes in supply costs in the proposed SUD Administrative Rules. There are no increases to administrative costs.

Licenseses that are required under the current and proposed SUD Administrative Rules to perform drug testing will see a reduction in costs since the frequency of testing has been reduced to align with federal guidelines.

23. Identify the nature and estimated cost of any legal, consulting, or accounting services that small businesses would incur in complying with the proposed rules.

There are no legal, consulting or accounting services that would be incurred.

24. Estimate the ability of small businesses to absorb the costs without suffering economic harm and without adversely affecting competition in the marketplace.

There are no additional or new costs for small businesses since the rules do not make a distinction between small businesses or other sized businesses. There are no new costs directly presented for any business type. There will be a potential for cost reduction due to the expansion of the type of counselors that can be employed in licensed facilities and the branch offices and mobile units that can provide SUD services, and this may reduce costs for licenseses.

25. Estimate the cost, if any, to the agency of administering or enforcing a rule that exempts or sets lesser standards for compliance by small businesses.

There is no additional cost to the agency beyond the current operational cost.

26. Identify the impact on the public interest of exempting or setting lesser standards of compliance for small businesses.

Exempting or setting lesser standards of compliance for small businesses with respect to SUD services programs may have a negative effect on the health, safety, and welfare of the citizens of Michigan.

27. Describe whether and how the agency has involved small businesses in the development of the proposed rules.

The bureau involved small business through the rules review process through informal informational meetings and opportunities to submit comments and suggestions. Informational seminars were hosted on November 9, 2021 and December 9, 2021.

A. If small businesses were involved in the development of the rules, please identify the business(es).

Licensees and stakeholders were emailed information about the informational sessions and participated in the question-and-answer sessions.

Cost-Benefit Analysis of Rules (independent of statutory impact)

28. Estimate the actual statewide compliance costs of the rule amendments on businesses or groups.

There is no statewide compliance cost of these rules on businesses or groups.

A. Identify the businesses or groups who will be directly affected by, bear the cost of, or directly benefit from the proposed rules.

There are no costs to groups or businesses, but the benefit of a streamlined rule set is consistency and modernization to meet current industry standards. These proposed rules will deregulate certain low-risk services from licensure, provide cost savings for certain remaining providers by allowing for branch and mobile locations at no additional licensing fee, and reduced staffing requirements for non-medical detoxification program. Prevention, assessment, and hospitals will save licensure fees of \$500 annually once these specific service categories are deregulated, as well as labor cost savings when provider staff are not required to spend time providing documents, answering questions, etc., during onsite licensing inspections that will no longer be required. In addition, outpatient programs will benefit from reduced costs as each branch office will no longer be required to have a separate license, which again is a \$500 annual savings per each branch site..

B. What additional costs will be imposed on businesses and other groups as a result of these proposed rules (i.e. new equipment, supplies, labor, accounting, or recordkeeping)? Please identify the types and number of businesses and groups. Be sure to quantify how each entity will be affected.

There will be no additional costs imposed on businesses or other groups as a result of these rules.

29. Estimate the actual statewide compliance costs of the proposed rules on individuals (regulated individuals or the public). Include the costs of education, training, application fees, examination fees, license fees, new equipment, supplies, labor, accounting, or recordkeeping.

There are no anticipated compliance costs to individuals as a result of the proposed rules.

A. How many and what category of individuals will be affected by the rules?

Licensed counselors and certified counselors could potentially be substituted with limited certified counselors within licensed SUD programs, potentially for the benefit of a lower individual wage cost. The primary difference would be that limited certified counselors have recipient-to-counselor ratios that are nearly half that of the other counseling professions. This could increase the opportunity for more facilities to hire additional counselors to meet the need during the current opioid overdose crisis. The total number of individuals affected by the rules is indeterminate.

B. What qualitative and quantitative impact do the proposed changes in rules have on these individuals?

The proposed SUD Administrative Rule change modernizes the rules to meet current industry standards in comparison to the existing rules and are similar to the rules used in neighboring states.

The impact to individuals includes an expansion of opportunities to utilize a wider range of counseling professionals for staffing at licensed facilities. The addition of limited certified counselors to fulfill licensing requirements will expand access to care for the public and increase employment opportunities for these counselors. The quality of care delivered to clients will remain the same as the limited certified counselors care can provide the same level of care to SUD recipients under their scope of practice. The primary differentiation in their services provided is that limited certified counselors have a lower recipient-to-counselor ratio than other counselors that can fulfill facilities' staffing requirements.

30. Quantify any cost reductions to businesses, individuals, groups of individuals, or governmental units as a result of the proposed rules.

The cost reductions to businesses, individuals, groups, or governments that are licensed under the current and proposed SUD Administrative Rules will be minimal but potentially measurable, and all cost reductions will be dependent on the choice of the licensee and not be driven by a requirement of the new rules.

Licensees, which could include businesses, individuals, groups, or governmental units, can choose to add limited certified counselors to staff under their licensure, although the recipient-to-counselor ratios for these counselors are lower than other counselors. Including limited certified counselors may potentially increase client revenue without substantially changing staffing costs or counts. Additionally, licensees could add a limited number of branch offices or mobile units to their licenses which will not increase the licensure fees.

31. Estimate the primary and direct benefits and any secondary or indirect benefits of the proposed rules. Please provide both quantitative and qualitative information, as well as your assumptions.

The benefits for the proposed SUD Administrative Rules include the following: clarification of when a license is needed, an expansion of the types of counseling professionals that can meet the staffing requirement for licensees, a streamlining and modernization of the regulations and the language terminology used therein, and an expansion of the types of licensed SUD services.

Other benefits include client safety and expanded access to services added in the form of branch offices and mobile units that increase service reach, expanded scope of staff development and training topics, the expansion of licensed withdrawal management programs, protocol to offer naloxone to recipients with a history of opioid use disorder, and the policy and procedure that may not permit the discharge of a recipient due to a return to use so long as the recipient reengages in treatment.

32. Explain how the proposed rules will impact business growth and job creation (or elimination) in Michigan.

The proposed rules will not adversely impact business growth or job creation in Michigan.

33. Identify any individuals or businesses who will be disproportionately affected by the rules as a result of their industrial sector, segment of the public, business size, or geographic location.

Limited certified counselors will see increased opportunities for employment within licensed SUD programs. The addition of licensure categories such as mobile units and branch locations may also lead to increased employment opportunities to the professionals who will staff these entities.

There is no disproportionate impact on the public, business size, or any specific geographic location due to the proposed rules. The impact on the public may only be expanded access to SUD services.

34. Identify the sources the agency relied upon in compiling the regulatory impact statement, including the methodology utilized in determining the existence and extent of the impact of the proposed rules and a cost-benefit analysis of the proposed rules.

When compiling information for the SUD rules and regulatory impact statement, the Bureau of Community and Health Systems (BCHS) relied on the following sources for compiling the regulatory impact statement: the Federal Drug Enforcement Agency (DEA), Substance Abuse and Mental Health Services Administration (SAMHSA), American Society of Addiction Medicine (ASAM), an analysis of border states to Michigan and similarly regulated states, including Illinois, Indiana, Minnesota, Ohio, and Wisconsin.

Additionally, the bureau hosted several meetings to utilize the input and ideas of all parties involved, including licensees, regional health agencies, small business license owners, the Department of Health and Human Services (DHHS), physician experts, and health professional associations. The bureau presented the proposed language and received direct feedback and suggestions in two informational seminars.

The cost-benefit analysis of the proposed SUD Administrative Rules shows that there is no direct change to the cost associated with licensing of SUD facilities, as the licensing fee remains the same and any additional new license applications will be offset by clearer and updated regulatory rules. There will be indirect benefits to licensees who utilize the opportunity to employ limited certified counselors that are now authorized to work in the licensed SUD environment. New facilities that will be required to be licensed will likely have costs offset with greater access to clients in need of treatment and rehabilitation and the reimbursement that follows for providing treatment and rehabilitation. Additionally, the licensure of branch offices and mobile units will allow licensees to expand access while – in many cases – not increasing their respective licensure fees. The proposed deregulation of buprenorphine and naltrexone will remove any burdens associated with SUD licensure costs and administrative processes for prescribers of these medications. The licensing fees and costs associated with staffing and operating a licensed SUD program in Michigan are equal to or cheaper in Michigan than other states in the Great Lakes region and beyond used in the rules research.

A. How were estimates made, and what were your assumptions? Include internal and external sources, published reports, information provided by associations or organizations, etc., that demonstrate a need for the proposed rules.

The estimates were made utilizing direct comparison of fee costs in other states, a review of the staffing requirements for states with similar SUD regulations such as Illinois, Indiana, Minnesota, Ohio, and Wisconsin, and a review of the types and services regulated in regional and similar situated states.

Since the regulation of SUD programs in Michigan already existed and the authority has not changed from the Public Act, this drafting of proposed SUD Administrative Rules focused on maintaining the existing regulatory structure but updating the language used, terminology, staffing requirements, and service categories utilized. This was analyzed and compared to the states of Wisconsin, Ohio, Indiana, and Illinois.

Overall, Michigan is on par with similar situated states and provides this licensing at a lower cost and permits greater flexibility in staffing and operation than the compared states as a whole.

Alternative to Regulation

35. Identify any reasonable alternatives to the proposed rules that would achieve the same or similar goals.

There are no reasonable alternatives to the proposed rules that have been identified that would achieve the same or similar goals.

A. Please include any statutory amendments that may be necessary to achieve such alternatives.

There are no statutory amendments that are necessary to achieve such alternatives.

36. Discuss the feasibility of establishing a regulatory program similar to that proposed in the rules that would operate through private market-based mechanisms. Please include a discussion of private market-based systems utilized by other states.

Extensive research and development would be needed to establish a regulatory program through private market-based mechanisms. Regulation of SUD services in neighboring states to Michigan are not private market-based, therefore no other models were available for evaluation.

37. Discuss all significant alternatives the agency considered during rule development and why they were not incorporated into the rules. This section should include ideas considered both during internal discussions and discussions with stakeholders, affected parties, or advisory groups.

There were no significant alternatives presented to the bureau to consider.

Additional Information

38. As required by MCL 24.245b(1)(c), please describe any instructions regarding the method of complying with the rules, if applicable.

Not applicable.