Report From Agency

RULEMAKING REPORT TO LEGISLATURE

CLEARINGHOUSE RULE 20-047

Ch. DHS 75

Basis and Purpose of Proposed Rule

Chapter DHS 75, regarding community substance use services, establishes minimum standards for treatment facilities concerning the health and safety of patients and distinguishing between facilities rendering differing types of treatment. (ch. 51.45(8)(a), Stats.)

In response to recommendations from the Governor's Task Force on Opioid Abuse, 2017 Executive Order 228 directed the department to revise ch. DHS 75 to better align with evidence-based practice standards in the industry and address gaps in service delivery related to the opioid epidemic in Wisconsin. Chapter DHS 75 establishes minimum standards for substance use prevention and treatment services delivered across a variety of settings and levels of care in Wisconsin. Chapter DHS 75 has not been substantially revised since 2010, and much of the terminology and structure no longer reflects the rapidly evolving field of behavioral healthcare and the needs of Wisconsin consumers.

Following extensive consultation with stakeholders in the substance use services community, the department proposes to update the rule chapter as follows:

- Revise the rule's terminology and structure to better align with the American Society of Addiction Medicine's (ASAM) standards and more clearly define and expand available levels of care for substance use disorder treatment.
- Incorporate recommendations from the Substance Abuse and Mental Health Services Association (SAMHSA) to better address integrated treatment for co-occurring substance use and mental health disorders.
- Incorporate standards that increase the adoption of best practices for the treatment of opioid use disorders and other substance use disorders, along with increasing overall flexibility for providers and reducing unnecessary barriers to the delivery of substance use prevention and treatment services.
- Align with more recent Medicaid requirements for substance use disorder services, and with revised professional licensing and credentialing standards from the Department of Safety and Professional Services.

Given the need for substantive changes related to practice standards of the profession, alternatives to rule revision would fail to address the ordered changes to ensure the adequate protection of Wisconsin consumers and availability of a full continuum of substance use services for Wisconsin citizens.

Department Response to Legislative Council Rules Clearinghouse Recommendations

The department accepts the recommendations made by the Legislative Council Rules Clearinghouse and has modified the proposed rule where suggested.

Final Regulatory Flexibility Analysis

The issues raised by each small business during the public hearing(s).

Opioid treatment programs (OTPs) shared analysis of increased costs associated with staffing requirements, caseload ratios, laboratory services, and service hours of operation in the proposed rule. The Wisconsin Hospital Association shared concerns that the rule is overly prescriptive, posing additional administrative costs.

Any changes in the rule as a result of an alternative suggested by a small business and the reasons for rejecting any of those alternatives.

In regards to these concerns, several modifications were made to the proposed rule as follows:

Staffing requirements:

- The requirements and definition for a medical director under DHS 75.03(52) and DHS 75.59(5)(b) were modified to include physicians "knowledgeable in addiction treatment with one year of addiction medicine experience", rather than requiring addiction medicine certification.
- The OTP requirement for a medical director to be on-site at least 40% of the time dosing is occurring was modified to allow for the medical director, service physician, or approved mid-level practitioner to fulfill this function. DHS 75.59(5)(b)

Caseload ratios:

- The limitation on caseloads for clinic directors was removed and modified to “a caseload of patients that is reasonable to ensure prompt and adequate access to care”. DHS 75.59(5)(a)
- The requirement for a service to have one full time nurse for every 200 patients was removed from the proposed rule. DHS 75.59(5)(c)
- The caseload limit for clinical supervisors was increased from 25 to 30. DHS 75.59(5)(f)

Hours of operation:

- The requirement for OTP’s to be open 7 days per week, 365 days per year was modified to: “Dosing and counseling shall be available at least six hours per day from Monday through Friday and at least one hour on Saturday. On Sundays, dosing shall be available and counseling may be provided to meet patient needs. (c) Daily operations. All clinics must be open for dosing and counseling at least 6 days per week and shall be open on Sundays if they have any patients that do not meet criteria for take home medication if those patients cannot be served via guest dosing at other nearby clinics.” DHS 75.59(8)(b) and (c)

Laboratory services:

- The requirement for urine drug testing for ethyl-glucuronide to detect possible alcohol use was modified to “Alcohol testing will occur for individuals with a history of alcohol use disorders and when concerns exist.” DHS 75.59(15)(a)1.

Additional requirements were removed from sections 75.20(4) regarding staff development, 75.25(4) regarding safety planning, 75.25(10) regarding interim services for pregnant women, and 75.26 regarding outcome monitoring and quality improvement, to reduce overall prescriptiveness of the proposed rule.

The nature of any reports and estimated cost of their preparation by small businesses that must comply with the rule.

Not applicable, no reports from small businesses are required to comply with the proposed rule.

The nature and estimated costs of other measures and investments that will be required by small businesses in complying with the rule.

The proposed rule changes are estimated to result in an overall cost savings statewide, with the removal of specific staffing requirements and the options for integrated certification for some service types.

The proposed rule reduces certification requirements for substance use prevention services, integrated substance use and mental health outpatient services, emergency services, ambulatory detoxification services, and substance use services provided in medical settings. The proposed rule removes the requirement for a medical director for outpatient substance use services and outpatient integrated behavioral health services. The proposed rule also allows for the option of reduced certification requirements for residential substance use treatment services.

The reason for including or not including in the proposed rule any of the following methods for reducing the rule’s impact on small businesses, including additional cost, if any, to the department for administering or enforcing a rule which includes methods for reducing the rule’s impact on small businesses and the impact on public health, safety and welfare, if any, caused by including methods in rules

The proposed rule reduces and aligns provider requirements for integrated services related to mental health and substance use treatment, for residential substance use treatment services, and for various provider types that deliver substance use treatment services. The proposed rule removes requirements for duplicative signatures on documents, as well as prescriptive service evaluations and staff development plans.

In areas where additional requirements are proposed, these are in compliance with 2017 Executive Order 228 to include practices related to the treatment of opioid use disorders.

Changes to the Analysis or Fiscal Estimate/Economic Impact Analysis

Analysis

No changes were made to the rule's analysis.

Fiscal Estimate/Economic Impact Analysis

No changes were made to the rule's fiscal estimate/economic impact analysis.

Public Hearing Summary

The department began accepting public comments on the proposed rule via the Wisconsin Legislature Administrative Rules website, and through the Department’s Administrative Rules Website on October 27, 2020. A public hearing was held on November 13, 2020, via Zoom online platform. Public comments on the proposed rule were accepted until 11:59pm on November 13, 2020.

List of the persons who appeared or registered for or against the Proposed Rule at the Public Hearing.

Registrant	**Position Taken** (Support or Opposed)
Due to the public hearing being held virtually, registration was not feasible. There were a total of 279 participants on the Zoom platform during the most attended portion of the hearing. The names of individuals that provided comments during the hearing are included below.	
Angela Eggum	Oppose
Bob McManimon-Moe	Neither
Chad Pergandy	Oppose
Christina Schiller	Oppose
Christine Ullstrupp	Neither
David Galbis-Reig	Support
David Macmaster	Support
Deb Croatt	Neither
Denise Johnson	Neither
Don Zukowski	Oppose
Dwain Berry	Neither
Harold Gates	Neither
James Reider	Oppose
Joseph Hefter	Neither
Kay Christianson	Oppose
Kent Barnes	Oppose
Kirk Yauchler	Neither
Lesley Wimmer	Neither
Luke Mohr	Oppose
Mark Wakefield	Oppose
Michael Errico	Oppose
Michael Goldstone	Neither
Michael Kemp	Neither
Michael Owen	Neither
Nancy Richardson	Oppose
Reuben Steindorf	Oppose
Sara Aranda	Neither
Sharel Rogers	Oppose
Sue Beattie	Neither
Teddy Thompson	Oppose
Tekia Longstreet	Oppose

Terri Ellzey	Neither
Tina Baeten	Neither
Tom Bolan	Oppose
Vanessa Baumann	Neither

Summary of Public Comments to the Proposed Rule and the Agency's response to those comments, and an explanation of any modification made in the proposed rule as a result of public comments or testimony received at the Public Hearing.

Rule Provision	Public Comment	Department Response
	Overall, 91 individuals or organizations provided written or verbal comments, which are summarized below under each respective subsection of the proposed rule. The number of comments and content are included for each proposed rule item and departmental response.	
General	The department received 1 comment stating that the proposed rule is too lengthy and overly prescriptive.	The proposed rule outlines minimum standards concerning the health of patients and distinguishing between different types of treatment, as required in ch. 51.45(8)(a), stats. DHS 75 covers 15 distinct service types and levels of care. While the rule is lengthy due to this scope, certified service providers are only required to comply with the requirements set forth in the sections of the rule applicable to their service and setting. Some areas of the proposed rule, while adding length to the overall text, have been incorporated expressly to add increased flexibility in certification options and service delivery. The proposed rule also reduces several costly requirements, resulting in net savings for providers. The proposed rule also includes exemptions from certification in several service areas, notably for most services delivered in primary medical settings. The department has further reviewed rule language in consideration of this feedback and made the following changes: - Several definitions were removed, clarified or shortened, or moved under specific subchapters, where applicable. - DHS 75.20(4) Staff development: "The requirements in this subsection may be met through documentation on an employee's annual performance evaluation that addresses professional development goals" was added to increase flexibility. - DHS 75.25(4) Safety planning: Requirements (c)-(f) were removed to reduce the prescriptiveness of this section. - Requirements under DHS 75:26 Outcome monitoring and quality improvement plan were reduced and simplified.
General	The department received 1 comment stating: "Having one rule for all areas of the state, especially rural areas, threatens these efforts	The proposed rule establishes minimum requirements that are applicable to services across the state, but also increases flexibility for

	and risks that programs won't be financially sustainable."	providers in several areas, including allowable staff and service types; flexibility of policies, procedures, and certification options; reducing administrative requirements; and better aligning with other administrative rules, provider credentialing, and service delivery models. The rule revision process included input from providers across the state and considered the broad range of services, settings, and needs addressed in the rule.
General	The department received 1 comment requesting for language concerning "evidence-based" practices to be incorporated into the rule.	The proposed rule is statutorily required to adhere to minimum standards for treatment services. As such, references to evidence-based treatment practices in the proposed rule are limited to DHS 75.59(4)(L) and DHS 75.60(4)(h), consistent with 2017 Executive Order #228. In accordance with feedback received from some stakeholders that the term "evidence-based practices" is not inclusive of all cultural practices for treatment services and models for healing, the term used in the proposed rule is "evidence-based practices, emerging best practices, and promising practices".
General	The department received 1 comment that the proposed rule should ensure that all professionals working in substance use treatment services are appropriately credentialed and possess appropriate certifications and credentials.	Professional credentialing requirements are established under the Wisconsin Department of Safety and Professional Services and are outside the scope of the department.
General	The department received 1 comment indicating that the proposed rule should regulate recovery houses and peer support centers.	Regulation of recovery houses and peer support centers is outside the approved scope for the DHS 75 revision.
General	The department received 1 comment stating that it's difficult for providers to financially sustain operations without grant funding due to provider types that are misaligned with reimbursement benefits.	The department is working closely with Medicaid to identify and address any areas of misalignment with Forwardhealth policy under the current and proposed DHS 75 rules. The proposed rule expands allowable provider types and treatment services to improve flexibility for providers that may aid in reducing operational costs and allowing for increased reimbursement.
General	The department received 2 comments requesting clarification regarding requirements for clinical supervision, Department of Safety and Professional Services form #2749, and 2017 Act 262.	Requirements related to professional credentialing are established by the Department of Safety and Professional Services (DSPS) and are outside the scope of DHS.
General	The department received 1 comment concerning inappropriate prescribing of opioids by primary care physicians.	The department agrees that opioid over-prescribing and inappropriate prescribing of opioids, benzodiazepines, and other addictive medications is of concern. The proposed DHS 75 rule provides minimum standards for community substance use services to support safe and appropriate service delivery, including medications for the treatment of behavioral health needs. Primary care services are outside the scope of the DHS 75 rule, however, DHS supports the Wisconsin Prescription Drug Monitoring Program, prescriber training,

		universal screening for substance use disorders in primary care, and interventions addressing the practices of outlier prescribers in regards to this practice.
General	The department received 1 comment stating that the proposed rule is complex and difficult to understand and requesting a document that highlights specific changes.	The proposed rule repeals and recreates DHS 75, so there is no document with tracked or highlighted changes due to the restructuring of the chapter. The department has, however, provided a revision summary document on the DHS Administrative Rules webpage that may be helpful as an overview of substantive changes and tips for providers reading the proposed rule.
General	The department received 1 comment stating that there are no SUD providers in WI for deaf who can sign.	The department continues to ensure that gaps in behavioral health services are identified and addressed, including the recent Wisconsin Behavioral Health System Gaps Report. The proposed rule also incorporates requirements for programs to have policies regarding culturally and linguistically appropriate services (proposed DHS 75.25(8)).
General	The department received 1 comment to ensure that person-centered language is used throughout the rule, including references to trauma-informed care.	Although the department supports these practices and incorporates standards throughout the rule to ensure patient rights and access to safe, appropriate, and responsive services, the proposed rule is statutorily required to adhere to minimum standards for treatment services.
General	The department received 1 comment requesting for all references to “substance abuse” and “alcohol and other drug abuse” in the proposed rule be changed to “substance use disorder”.	These terms have been modified throughout the proposed rule, except in instances where the language refers to a specific program title (such as DHS 62), other administrative rule, or professional credential type certified by DSPS (as in the case of “substance abuse counselor”). In these cases, the terms were retained to avoid confusion.
DHS 75.03(19)	The department received 12 comments that licensed mental health professionals are not competent to supervise substance abuse counselors without specific training and experience. Commenters requested for additional requirements to be added for licensed mental health professionals to act as clinical supervisors of substance use services.	2017 Act 262 modified statute 440.88(3m), and allows licensed mental health professionals to act as clinical supervisors of substance use services. Modifications of this statute are outside the scope of DHS 75. The proposed rule language represents efforts to establish some measure of experience within the current statutory exemption.
DHS 75.03(19)	The department received 1 comment supporting the proposed requirements related to licensed mental health professionals providing clinical supervision.	No response needed.
DHS 75.03(28)	The department received 2 comments requesting for the CLAS Standards to be required in the proposed rule.	The proposed rule includes the addition of DHS 75.25(8), along with the definition for culturally and linguistically appropriate services under DHS 75.03(28), and requires certified treatment services to have a written policy and procedure for assessing the cultural and linguistic needs of the population to be served, and to ensure that services are responsive and appropriate to the cultural and linguistic needs of the community to be served.

DHS 75.03(78)	The department received 2 comments concerned that the proposed definition for “intern” did not include undergraduates.	This definition was removed from the proposed rule. A definition for qualified treatment trainees was added, rather than interns, to reduce confusion.
DHS 75.03(52)	The department received 4 comments stating that the requirement for a medical director to possess certification in addiction medicine represents a hardship due to a shortage of eligible providers that possess this specialty certification.	The definition was modified to include “physicians knowledgeable in addiction treatment or working toward certification in addiction medicine or addiction psychiatry”.
DHS 75.03(52)	The department received 2 comments supporting the requirement that a medical director be certified in addiction medicine.	The department agrees that certification in addiction medicine is preferred to ensure adequate training in the treatment of substance use disorders, however, due to the significant feedback from providers that this requirement represents a hardship related to current workforce capacity, the options for “knowledgeable in addiction treatment or working toward certification in addiction medicine or addiction psychiatry, with one year of experience in addiction medicine” were added.
DHS 75.03(78)	The department received 1 comment that the definition language distinguishing psychoeducation from group therapy was inconsistent with the practice of these services.	This language was removed from the proposed rule.
DHS 75.03(80)	The department received 2 comments requesting for the credentials, training, and scope of practice for recovery coaches to be defined in the rule.	Defining the credentials, training, and scope of practice for recovery coaches is outside the scope of DHS 75.
DHS 75.03(103)	The department received 1 comment stating that the proposed rule definition for “unlicensed staff” differs from DSPS use of this term.	The department attempted to align with DSPS credentialing terms to the extent possible, however, this distinction in the proposed rule was necessary to distinguish differing requirements for clinical staff that are independently licensed from those that possess in-training credentials or qualified treatment trainees throughout the rule.
DHS 75.07	The department received 1 comment in support of the change to biennial fees and certification.	No response needed.
DHS 75.13	The department received 1 comment that the inclusion of telehealth was welcomed and aligned with telehealth expansion policies and practice.	No response needed.
DHS 75.23	The department received 1 comment that the requirements outlined for services to minors are welcomed and provide adequate flexibility for providers.	No response needed.
DHS 75.25(7)	The department received 7 comments supporting the inclusion of tobacco use disorder treatment and facility policies in the proposed rule. One commenter requested that this provision go further to require smoke-free facilities and provide specific guidance and model language for related policy.	The rule is statutorily required to adhere to minimum standards, thus the requirement for all facilities in the state to be smoke-free was not prescribed in the rule. Additional best practice recommendations and guidance supporting tobacco integration and smoke-free treatment facilities can, however, be issued and supported by the department through other activities, such as technical assistance, contractual

		requirements, guidance documents, and best practice promotion.
DHS 75.25(10)	The department received 1 comment that proposed requirements for interim services for pregnant women represent a burden for providers and would be best provided by public health.	The proposed requirements align with state and federal requirements regarding priority admission and wait time reporting. The proposed rule language regarding interim services was modified, however, as this federal requirement only applies to agencies that receive any contracted federal funds. The following language was removed: "(c) At a minimum, interim services shall include counseling and education about communicable illnesses, the risks of needle-sharing, the risks of disease transmission to sexual partners and infants, and about steps that can be taken to ensure that HIV, hepatitis, and tuberculosis transmission does not occur, as well as referral for HIV, hepatitis, or tuberculosis treatment services, if necessary. For pregnant women, interim services also include counseling on the effects of alcohol and drug use on the fetus, as well as referral for prenatal care."
DHS 75.25(11)	The department received 1 comment requesting the inclusion of spirituality as a required area of the psychosocial assessment.	Although spirituality is not specifically identified as a requirement of the assessment, "(i) Other factors that appear to have a relationship to the patient's substance use and physical and mental health" may include spirituality, as applicable.
DHS 75.25(11)	The department received 2 comments requesting training resources or a state-issued format for ASAM criteria screening.	The proposed rule allows for ASAM or other department-approved placement criteria. The department is not able to develop or issue a document for ASAM assessment, as this would be in violation of fair use and copyright laws. Many providers have developed their own format for ASAM assessment and these may be available for sharing with other professionals or agencies. Lastly, the department offers ASAM training through several conferences or other opportunities annually.
DHS 75.25(13)(c)	The department received 1 comment requesting to add "other support system as identified by the patient", in addition to family participation in treatment planning.	This language was added to the proposed rule.
DHS 75.25(15)(c)4.	The department received 2 comments that the proposed requirement for documentation of clinical staffing in a log is inconsistent with HIPAA.	This proposed requirement was modified to reflect documentation in a patient record.
DHS 75.36(2)	The department received 2 comments stating that the proposed requirement for separation of residential services for parents with residing minors needed clarification or may be prohibitive due to facility limitations.	The proposed rule language was modified to indicate that a residing family shall not share a bedroom with other residents of the service.
DHS 75.37	The department received 1 comment that the requirement for "arrangements" with medical facilities are often not permitted or necessary.	This language regarding "arrangements" was removed from the proposed rule.
DHS 75.48(2)(h)/ DHS 75.54	The department received 1 comment requesting to remove the requirement for the physician review of assessment and level of care placement within 7 days.	This requirement in the proposed rule was changed to: "A physician, physician assistant, registered nurse, or clinical supervisor shall review and co-sign the assessment and level of

		care placement within 7 days of the assessment."
DHS 75.50	The department received 2 comments requesting clarification regarding the proposed level of care for integrated outpatient behavioral health services and requirements in this section.	The department will provide technical assistance and support for agencies wishing to certify under this new level of care, if the proposed rule is approved. The following language was removed from the proposed rule, to reduce confusion: "(2) Combined Certification. Certification for this level of care shall not be located with s. DHS 75.49 outpatient substance use treatment service or with a ch. DHS 35 community mental health treatment service at the same service location.
DHS 75.50	The department received 1 comment in support of the proposed integrated outpatient behavioral health service level of care.	No response needed.
DHS 75.50 and DHS 75.53	The department received 1 comment that treatment plan reviews should be required more frequently for outpatient level of care and transitional residential level of care in the proposed rule.	The proposed rule must adhere to the minimum standard for services, in addition to aligning with ASAM levels of care for frequency of treatment plan review, as well as aligning with other similar rule requirements (DHS 35 for outpatient mental health and integrated services).
DHS 75.52/ DHS 75.48(1)(a)	The department received 1 comment that the proposed increase in hours of service for day treatment level of care will contribute to challenges receiving reimbursement for additional hours of service.	The billing code H2012 for partial hospitalization or intensive outpatient services is based on fee for service, with the same rate at each level of care per 15 minutes of services. The proposed increase in hours of service for day treatment is both consistent with ASAM levels of care and able to be billed under this fee for service model. In the proposed rule levels of care, programs will have the option to certify under the new IOP level of care, which requires a minimum of 9 hours of treatment services per patient per week, or increase hours of service to certify as day treatment level of care, which requires a minimum of 15 hours of service per patient per week.
DHS 75.54	The department received 3 comments stating that the increased requirements for treatment plan review for residential treatment services will increase clinician workload and are not aligned with Medicaid requirements.	Treatment plan review requirements in the proposed rule are aligned with ASAM levels of care, based on frequency and intensity of the service. Given that a length of stay for residential treatment may only be 30 days or less, and that this level of care represents high acuity, a review occurring at 30 day intervals is not appropriately matched to patient needs or this level of service. (The ASAM Criteria, p.110) The Forwardhealth policy regarding prior authorization may outline different timeframes for authorization of services, however, this is different than treatment plan review.
DHS 75.56	The department received 1 comment that the requirement for medical staff to be available "on-site" is problematic and does not allow for telehealth or other non-medical staff to meet the staffing requirement.	Language in proposed DHS 75.56(1) was modified to clarify that physician monitoring is required to be "available", rather than "on-site".

DHS 75.59	The department received 23 comments from patients of opioid treatment services affirming the importance of this service in their recovery.	The department appreciates the input of consumers of substance use services regarding the proposed rule and supports ensuring that opioid treatment services are accessible, safe, and effective.
DHS 75.59(1)	The department received 1 comment that medical services included for opioid treatment programs are outside the scope for an Opioid Treatment Program (OTP).	The proposed rule indicates that a service "may" provide medical services and is consistent with 42 CFR 8.12(f)(1) and SAMHSA TIP #43.
DHS 75.59(4)(a)	The department received 1 comment that the authority of the State Opioid Treatment Authority (SOTA) in recommending evidence-based practices is too broad.	The proposed rule language is consistent with 2017 Executive Order #228.
DHS 75.59(4)(j)	The department received 1 comment that the proposed rule should prohibit the use of service need data in the determination of approval for an OTP location.	There is nothing in this portion of the proposed rule regarding approval of an OTP location based upon service need. DHS continuously conducts needs assessments regarding services in the state and provides feedback on where services may be needed. Approval of service sites appears later in the rule under DHS 75.59 (21)(b): (b) Approval of service sites. Only service sites approved by SAMHSA, the DEA and the SOTA may be used for treating persons with an opioid use disorder with a narcotic drug. SAMHSA requires that a SOTA approve of any site in a state in writing, and therefore this decision lies with the SOTA.
DHS 75.59(4)(k)	The department received 5 comments that the SOTA's authority to place a hold on OTP admissions risks limiting access to care.	This provision was removed from the proposed rule.
DHS 75.59(5)(a)	The department received 1 comment that the proposed caseload limitation for clinic directors is too restrictive.	This language in the proposed rule was amended to: "a caseload of patients that is reasonable to ensure prompt and adequate access to care of those patients while balancing their other business responsibilities to the clinic."
DHS 75.59(5)(b)	The department received 9 comments that the proposed requirement for a medical director to be certified in addiction medicine is unnecessary, and limits the pool of candidates available for this role due to workforce shortages for qualified physicians.	This language in the proposed rule was modified to: "shall have at least one year of experience in addiction medicine or addiction psychiatry".
DHS 75.59(5)(b)	The department received 4 comments that the proposed requirement for the medical director to be physically present at least 40 percent of the time that medication is being administered or dispensed is overly burdensome.	The proposed rule text has been updated to: DHS 75.59(5)(b): Medical director. The service shall designate a physician licensed under ch. 448, Stats., as its medical director. The medical director shall have at least one year of experience in addiction medicine or addiction psychiatry, be licensed to practice medicine or osteopathy, and meet all other requirements listed in s. DHS 75.03 (52). The medical director, service physician, or mid level practitioner that has a federal exception approved by SAMHSA and the SOTA to 42 CFR 8.12 (b), (e), (h), and (i) shall be physically present at the OTP at least 40 percent of the time that the program administers or dispenses medication in order to comply with s. DHS

		94.08, assure regulatory compliance, and carry out duties specifically assigned by assure regulatory compliance, and carry out duties specifically assigned by regulation as required by SAMHSA under 42 CFR 8.12. OTPs in the first 60 days of operation may reduce the time requirement a practitioner must be present on site to at least 20 percent of the time that the program administers or dispenses medication. On the 61st day of operation the service shall be subject to the requirements of this rule. In order for an OTP to admit a person to treatment they must be determined eligible for services by the medical director, the service physician, or an approved mid-level practitioner. Ensuring that one of these three provider types is on-site at least 40% of the time medication is being dispensed will increase access to care. "The medical director is responsible for monitoring and supervising all medical and nursing services provided by the OTP. The medical director should have completed an accredited residency training program and have at least 1 year of experience in addiction medicine or addiction psychiatry. Board certification in his or her primary medical specialty and in addiction psychiatry or addiction medicine is preferred. (Federal OTP Guidelines, page 11). The medical director should be present at the program a sufficient number of hours to assure regulatory compliance and carry out those duties specifically assigned to the medical director by regulation. (Federal OTP Guidelines, page 11). DHS expanded this requirement to include service physicians and approved mid-level practitioners and set it at 40% of the time that "the program administers or dispenses medication," not when a service is in operation. Programs administer medication for a much shorter period of time than their hours of operation. A physician can gain the one year of experience by working in the OTP but cannot become a medical director of the OTP until they have the experience. The 40% requirement equates to a little under 14 hours per week except for the 24/7 OTP. This rule mirrors the requirement in Ohio. Indiana requires that for every 1,000 patients a FTE program physician be present at each OTP for forty (40) hours per week. They are currently working on a rule that reduces this expectation from 40 hours to 20 hours. In Pennsylvania, each OTP must have a physician provide methadone services for at least one hour per week for every ten patients
DHS 75.59(5)(c)	The department received 3 comments that the proposed requirement for a registered nurse to be physically on the premises any time dosing is	Currently OTP's are required to have an RN on-site anytime dosing is occurring pursuant to a DSPS decision regarding the acuity of patients

	occurring results in excessive cost and does not recognize the contributions of LPN's.	served within an OTP. https://www.dhs.wisconsin.gov/publications/p01277.pdf DHS updated the proposed rule language to: DHS 75.59(5)(c): Nurses. The service shall have a registered nurse on staff to supervise the dosing process and perform other functions delegated by the physician. A registered nurse shall be physically on the premises any time dosing is occurring.
DHS 75.59(5)(c)	The department received 2 comments that the proposed requirement to have one full time nurse for every 200 patients is overly burdensome.	This requirement was removed from the proposed rule.
DHS 75.59(5)(f)	The department received 2 comments stating that the proposed requirement for one full time clinical supervisor for every 10 counselors is overly restrictive.	SAMHSA TIP 52: Clinical Supervision and Professional Development of the Substance Abuse Counselor (pg. 32) states: "The number of supervisees reporting to a supervisor. It is difficult to provide the scope of supervision discussed in this TIP if a supervisor has more than ten supervisees. In such a case, another supervisor could be named or peer supervision could be used for advanced staff." Clinical Supervision requirements require a SAC-IT to receive weekly clinical supervision for 2 hours for every 40 hours worked. This will ensure that adequate supervision is provided to the staff as well as ensuring that the patients assigned to a clinical supervisor also receive access to prompt and adequate care. The 1:10 ratio also aligns with SAMHSA recommendations for clinical supervision.
DHS 75.59(5)(f)	The department received 2 comments stating the proposed restriction for clinical supervisors carrying a caseload over 25 persons is overly restrictive.	The requirement in the proposed rule was modified to: "The clinical supervisor shall not carry a caseload greater than 30 patients to ensure access to prompt and adequate care of those patients while balancing their clinical supervision responsibilities." OTP's have the ability at any point in time to request a variance or waiver to a rule if there are sudden or unexpected changes to their staffing patterns that result in needing to go over the limit permitted by rule.
DHS 75.59(5)(g)	The department received 1 comment that language clarifying and expanding the allowable role for physician's assistants should be added to the proposed rule.	The department agrees with the proposed change and has modified the rule to include this language.
DHS 75.59(6)(a)2.	The department received 2 comments stating that the requirement for a patient to meet diagnostic criteria for an opioid use disorder for one year prior for maintenance treatment restricts access to services.	This requirement is pursuant to 42 CFR 8.12(e)(1).
DHS 75.59(6)(e)1.	The department received 1 comment stating that proposed requirements for HIV testing for OTP's should include language about informed consent.	The rule was modified to read: "The comprehensive physical examination shall be ordered by the service physician on the day of admission and shall include a complete blood count and liver function testing. The service

		shall test for Hepatitis A, B, C and HIV if the patient gives informed consent in writing. If the patient declines permission to test shall be documented in the patient's record."
DHS 75.59(6)(k)1.	The department received 1 comment that requirements for notification of capacity and waitlist were overly burdensome.	OTP's already provide a weekly report to the SOTA regarding their capacity due to the current counselor to patient ratio regulation.
DHS 75.59(8)(a-e)	The department received 6 comments that the proposed requirements for OTP's to be open 7 days per week and 365 days per year are overly burdensome for providers and patients.	The requirement in the proposed rule was changed to: "(b) Availability of dosing and counseling. Dosing and counseling shall be available at least six hours per day from Monday through Friday and at least one hour on Saturday. On Sundays, dosing shall be available and counseling may be provided to meet patient needs. (c) Daily operations. All clinics must be open for dosing and counseling at least 6 days per week and shall be open on Sundays if they have any patients that do not meet criteria for take home medication if those patients cannot be served via guest dosing at other nearby clinics."
DHS 75.59(11)(c)	The department received 1 comment stating that proposed prohibitions regarding patient sanctioning should be removed.	This requirement currently exists within DHS 75 and is retained. "Patients in OTPs depend on their medication and may fear the effects of withdrawal from it. That dependence gives providers (and the principle of beneficence) the upper hand. Patients who refuse to comply with provider views of what is in their best interests risk administrative discharge or other sanctions. Until recently, only an OTP could provide patients with medication, ensuring the OTP's hold over patients. Often no other facility exists from which to obtain MAT." SAMHSA TIP 43: Medication Assisted Treatment For Opioid Addiction in Opioid Treatment Programs
DHS 75.59(13)(j)4.	The department received 1 comment stating that OTP's should have ability to modify or cancel take-home privileges.	This rule currently exists within DHS 75. A patient already has to meet multiple criteria in order to obtain take home medication and should not have it removed due to something outside of the required federal and state criteria.
DHS 75.59(13)(m)	The department received 1 comment stating that clinical probation requirements should be removed from the proposed rule.	This rule currently exists within DHS 75.
DHS 75.59(15)(a)1.	The department received 2 comments requesting consideration of removing the requirement for drug testing related to THC.	THC is an illicit substance at the state and federal level. Eight point criteria for take home medication requires: "Absence of recent abuse of drugs (opioid or nonnarcotic), including alcohol". In order to ensure a patient meets point one of the eight point criteria for take home medication, drug testing for THC will remain.
DHS 75.59(15)(a)1.	The department received 1 comment that the proposed requirement for urine ethyl-glucuronide testing is overly burdensome for providers and cost prohibitive.	The language was changed to: "Alcohol testing will occur for individuals with a history of alcohol use disorders and when concerns exist."
DHS 75.59(15)(b)	The department received 2 comments stating that the proposed requirements related to blood testing for serum methadone levels should not	The proposed rule decreases the frequency regarding this test from the current requirement of "at admission, three months, 6 months, and yearly" to annually or when split dosing is

	be prescribed in the rule, but determined by clinical staff.	requested. An evaluation of peak and trough methadone levels can help to determine if patient may be a “rapid metabolizer” who might benefit from a “split dose” instead of an increased daily dose. A patient can be evaluated for being “rapid metabolizer” by testing peak and trough levels of methadone. A peak and trough ratio of 2:1or greater implies patient might benefit from a split dose.
DHS 75.59(16)(a)1. and 4.	The department received 1 public comment stating the proposed requirements related to patient retention are too broad and not in keeping with business practices.	The provisions required in DHS 75.59(15)1. and 4. have been removed from the proposed rule.
DHS 75.59(17)(b) through DHS 75.59(18)(g)	The department received 1 comment stating that proposed requirements concerning co-occurring treatment and services for pregnant women are outside the scope of the OTP.	Federal OTP Guidelines: Every pregnant patient in an OTP should receive prenatal care, provided either onsite or by other healthcare providers. If appropriate prenatal care is neither available onsite nor by referral, or if the pregnant patient cannot afford care or refuses prenatal care services, an OTP, at a minimum, should offer basic prenatal instruction on maternal, physical, and dietary care as part of its counseling services. In cases where the OTP refers the patient elsewhere for prenatal care, the program should have formal documented agreements and informed consent procedures in place that ensure reciprocity in the exchange of pertinent clinical information regarding compliance with the recommended course of medical care. If a pregnant patient refuses the offered onsite or referred prenatal services, the treating physician or authorized healthcare professional, as appropriate, may use informed consent procedures to have the patient formally acknowledge, in writing, her refusal of these services. OTP’s are currently providing concurrent treatment for a patient diagnosed with both a mental health disorder and a substance abuse disorder and have been required to provide this service since 2008. Federal OTP Guidelines: “Medication-assisted treatment providers should have an understanding of both substance use and co-occurring disorders. It is essential for OTPs to develop a referral and consultative relationship with a network of agencies and providers capable of providing primary and specialty services for the range of psychiatric comorbid conditions, medical complications, and communicable diseases that may be part of a patient’s problem list if those services are not offered onsite. Increasingly, it is expected that substance abuse and mental health treatment programs will integrate medical and behavioral health services into their clinical programs in order to address the needs of the whole person receiving treatment services. OTPs may be

		especially well positioned to do this because they are already required to offer medical and substance use disorder treatment in a single setting. Information exchange across this network must both facilitate treatment and protect patient privacy. Medication-assisted treatment providers should have an understanding of both substance use and co-occurring disorders. It is essential for OTPs to develop a referral and consultative relationship with a network of agencies and providers capable of providing primary and specialty services for the range of psychiatric comorbid conditions, medical complications, and communicable diseases that may be part of a patient's problem list if those services are not offered onsite. Increasingly, it is expected that substance abuse and mental health treatment programs will integrate medical and behavioral health services into their clinical programs in order to address the needs of the whole person receiving treatment services. OTPs may be especially well positioned to do this because they are already required to offer medical and substance use disorder treatment in a single setting. Information exchange across this network must both facilitate treatment and protect patient privacy. An OTP identifies patients with mental health needs during the assessment process and refers them to appropriate treatment if such treatment is not available onsite. In addition, it monitors patients for the emergence of symptoms of mental illness when patients withdraw or are discharged from treatment. Linkages with mental health providers in the community provide a mechanism for an OTP to jointly monitor and evaluate a patient's use of mental health medication. If possible and when indicated, programs may dispense these medications in conjunction with the daily dose of opioid medication."
DHS 75.59(18)(f)7.	The department received 1 public comment stating that the recommendation to monitor blood serum levels for pregnant women should be determined through clinical judgment, not as a proposed requirement.	This is a recommendation and not a requirement within the rule.
DHS 75.59(20)(e)	The department received 1 comment that proposed requirements for facility security are overly burdensome and cost-prohibitive to hire security guards.	This rule currently exists within DHS 75 and does not require security guards. The federal guidelines mention "untrained security guards" as a privacy concern not all security guards. OTP's have scheduled narcotic drugs on-site and DHS has an obligation to ensure that "adequate" security measures are in place. DHS works closely with the DEA to ensure this occurs.
DHS 75.59(21)(b)4.	The department received 1 comment stating that the proposed requirements regarding diversion	The proposed rule language was modified to: "The service may discontinue take-home medications for patients who fail to return empty

	control should be changed to “allowed”, rather than “required”.	take-home bottles in the prescribed manner. If upon review of take home medication it is determined that medication is missing and cannot reasonably be accounted for the service shall discontinue take home medication.”
DHS 75.59(21)(c)	The department received 1 comment that the proposed requirement for service staff to address concerns related to diversion of medication with a patient immediately represents incorrect procedure from service staff consulting with counselors and medical staff first.	This rule currently exists within DHS 75. The proposed rule does not stop an OTP from developing a plan before communication occurs. It establishes that the counselor is responsible for addressing the issue with the patient.
DHS 75.59(21)(f)	The department received 2 comments stating that the proposed authority for the SOTA to revoke take-home medication privileges infringes upon the therapeutic relationship and clinical judgment of the service provider, and may disrupt access to care.	This rule currently exists within DHS 75. In 2020 over 1 thousand patients were incorrectly given take home medication where the OTP could not demonstrate that all requirements had been met when they granted the take home privileges. This rule gives the SOTA the ability to correct that issue in a swift manner to ensure the safety of patients and the community in which they reside.
DHS 75.59(21)(h)3.	The department received 1 comment stating that proposed language regarding call-backs for diversion control should allow for treatment team determination.	The proposed rule language in this section was updated by DHS earlier in the revision reprocess based upon recommendations from the OTP’s.
DHS 75.59(25)(d)	The department received 1 comment stating that proposed rule language concerning negative urine drug screens for guest dosing may disrupt a patient from their current treatment progress and phase of care.	The proposed rule includes the ability of the medical director to grant the guest dose privilege if they determine that the benefits of guest dosing outweigh the risks, and document the justification for granting guest dosing privileges in the patient’s record.
DHS 75.59(27)	The department received 2 comments that the proposed rule requirements for outreach services are outside the scope for OTP’s and overly burdensome.	This section was removed from the proposed rule.
DHS 75.60	The department received 2 comments stating concerns that the proposed rule section related to office-based opioid treatment (OBOT) was added after the last advisory committee meeting and did not afford the opportunity for discussion with the advisory committee.	DHS was working on this section until after the advisory committee meetings concluded and stakeholder meetings were held. The public including the advisory committee members have all been afforded an opportunity to provide feedback through the public comment time period.
DHS 75.60(1)	The department received 1 public comment that the proposed certification applicability for OBOT’s was ‘poorly defined and may inadvertently lead primary care providers to conclude that they cannot prescribe buprenorphine. This will scuttle efforts to develop a hub and spoke treatment model similar to what is in Vermont.’	The definition for an office-based opioid treatment program states that treatment that occurs in a primary care service or hospital setting is exempted from this rule. This definition language was moved from DHS 75.03 to DHS 75.60(1) for clarity. OBOT’s in the hub and spoke system in Vermont are under the oversight of the Vermont SOTA.
DHS 75.60(4)(4)	The department received 2 comments stating that “placing medical clinics under the SOTA that regulates methadone clinics is an unwise intrusion into medical practice.”	Pursuant to Chapter 51.4224(c): “State methadone authority” means the subunit of the department designated by the governor to exercise the responsibility and authority in this state for governing the treatment of a narcotic addiction with a narcotic drug.

		OBOT's treat narcotic addiction with a narcotic drug and therefore are under the oversight of the SOTA. Treatment provided in primary care clinics and hospitals are both exempted from this regulation and therefore would not be subject to these rules. 2017 Executive order 228: "The department should revise DHS 75 to grant the state's opioid treatment authority greater discretion to require certified clinics to embrace evidence based practices in treatment." The SOTA will work with OBOT practices to be able to continue to implement evidence-based practices that will change over time as advances are made in the field. The SOTA does not have the authority to "shut down" an agency as that would require decertification by the Division of Quality Assurance, but the SOTA would have the ability to stop admissions to a program due to safety concerns or violations of federal and or state rules while that agency came back into compliance. SAMHSA also has oversight of OBOT providers and relies on input from the SOTA regarding accelerating a provider's ability to treat more patients before they would normally be able to do so under federal laws based upon how long they have been certified to treat a specific amount of patients. The SOTA cannot provide this information to SAMHSA without having oversight. Chapter 51 already gives the SOTA the ability to complete unscheduled compliance surveys of any entity that is certified by the department.
DHS 75.60(7)(c)	The department received 2 public comments stating that the proposed requirement for OBOT services to include psychosocial treatment or referral for such services, is an intrusion into medical practice and may limit patient participation in MAT.	Proposed DHS 75.60(7)(c)4. allows for a patient to refuse psychotherapy/counseling and the physician only needs to document the refusal. The patient is still able to receive medication. The department has updated language in this section to include the term "prescriber," as physicians are not the only provider that is able to prescribe these medications.
Current DHS 75 Rule	The department received 2 comments related to the current DHS 75 rule, concerning the following areas: duplicative signature requirements, outdated terminology, lack of integration for mental health and substance use services, prescriptive clinical supervision requirements, recognition of electronic health records and telehealth service delivery, professional credentialing changes and recognition of additional provider types, group ratios, and requirements for written agreements for emergency medical services.	The areas and concerns identified are resolved in the proposed rule.
N/A	The department received 1 comment endorsing a specific smoking cessation service provider that was not related to the proposed rule.	No response needed.

Summary of Items Submitted with this Report to the Legislature

Below is a checklist of the items that are attached to or included in this report to the legislature under s. 227.19 (3), Stats.

Documents/Information	Included in Report	Attached	Not Applicable
Final proposed rule -- Rule Summary and Rule Text		X	
Department response to Rules Clearinghouse recommendations	X		
Final Regulatory Flexibility Analysis	X		
Changes to the Analysis or Fiscal Estimate/Economic Impact Analysis	X		
Public Hearing Summary	X		
List of Public Hearing Attendees and Commenters	X		
Summary of Public Comments and Department Responses	X		
Fiscal Estimate/Economic Impact Analysis		X	
Revised Fiscal Estimate/Economic Impact Analysis		X	
Small Business Regulatory Review Board (SBRRB) statement, suggested changes, or other material, and reports made under s. 227.14 (2g), Stats. and Department's response			X
Department of Administration (DOA) report under s. 227.115 (2), Stats., on rules affecting housing			X
DOA report under s. 227.137 (6), Stats., on rules with economic impact of $20 MM or more			X
Public Safety Commission (PSC) energy impact report under s. 227.117 (2), Stats. and the Department's response, including a description of changes made to the rule			X