STATEMENT OF SCOPE
WISCONSIN DEPARTMENT OF HEALTH SERVICES

CHAPTER: DHS 75, DHS 101, DHS 105, DHS 107

RELATING TO: Community substance use services standards; medical assistance certification and reimbursement for certain substance use services

RULE TYPE: Permanent and emergency

SCOPE TYPE: Original

FINDING OF EMERGENCY: An emergency rule is necessary to protect the public peace, safety, and welfare as these changes can be critical to accessing substance use disorder treatment services. The nation's drug overdose epidemic continues to worsen: there have been more than 107,000 deaths from overdose reported in the United States between January 2021 to January 2022, up from 72,000 between January 2019 and January 2020. Substance use treatment is in demand and access is limited, creating waiting lists for those in need of care. Wisconsin has the third-highest percentage of adults who drink alcohol and ranks third in the nation for binge drinking. Synthetic opioids, primarily fentanyl, have been identified in most opioid overdose deaths. Provisional data shows the number of fentanyl overdose deaths in Wisconsin grew by 97 percent from 2019 (651) to 2021 (1,280). The sharp increase in overdose deaths is not only impacting those who use opioids, as cocaine deaths involving synthetic opioids increased by 134 percent from 2019 (182) to 2021 (426). The proposed rules will reduce waitlists, increase access to care, and promote the best practice of integrated care to treat co-occurring mental health and substance use disorders—all of which are important and proactive steps to attempt to reduce overdose and death. The ability for citizens in Wisconsin to access appropriate treatment and community recovery resources is critical to improving the overall health of our citizens and reducing the impact of substance use disorders on individuals, families, and communities.

SUMMARY

1. Description of rule objective/s

The Wisconsin Department of Health Services ("the Department") proposes emergency and permanent rules relating to community substance use service standards. Generally, the proposed rules seek to remove regulatory barriers to increase access to treatment services, and update language that is outdated due to federal regulatory revisions.

The objectives of the proposed rule are as follows:

— Amend language in ch. DHS 75 for alignment with the new federal requirements and allowances in relation to substance use services, specifically regarding prescribing Schedule III Buprenorphine medication for opioid use disorders to more than 30 individuals.
— Amend provisions within outpatient applicability standards in ch. DHS 75 to include exemptions to certification requirements for DHS 35 certified outpatient mental health clinics and licensed rural health centers.

— Amend provisions within ss. DHS 75.51 and 75.52 to allow for integrated, mental health and/or substance use treatment within intensive outpatient, day treatment and partial hospitalization settings.
— Amend integrated residential crisis stabilization services in language in s. DHS 75.56 to allow the provision of services in community-based settings.
— Amend s. DHS 75.56 to allow for those in crisis, experiencing suicidal ideation, thoughts, etc. to be admitted for stabilization services when appropriate.
— Remove all references requiring hepatitis testing in various settings.

The department also proposes to amend ss. DHS 101.03, 105.23, and 107.13, and to create s. DHS 105.235 to include the creation of a more intensive level of care that is consistent with s. DHS 75.51, integrated intensive outpatient treatment service certification. The proposed changes will permit certification and reimbursement under MA for an intensity of treatment and level of service between outpatient and day treatment. The proposed changes will:

— Allow certified providers to implement evidence-based practices in treatment.
— Allow certified providers to offer and gain reimbursement for treatment to an appropriate level of care.
— Ensure that reimbursement is made for services subject to certification and quality standards.

In addition, the department proposes to revise rule language in chs. DHS 101, 105, and 107 to meet and align MA program coverage with the proposed program updates for intensive outpatient treatment, and to clarify qualified treatment trainee (QTT) and the staff who are qualified to provide and be reimbursed for substance use disorder (SUD) or alcohol and other drug abuse (AODA) treatment.

Finally, the department proposes to revise current MA day treatment rules in 105.24, 105.25, and 107.13 to align with changes that will be made in DHS 75.52. These changes will allow MA chapters to reflect an integrated level of service for day treatment for the first time and be aligned with current rules.

2. Existing policies relevant to the rule

Section DHS 75.60 currently requires that office-based opioid treatment providers have an approved Drug Addiction Treatment Act of 2000 ("DATA 2000") wavier from the federal Substance Abuse and Mental Health Services Administration ("SAMSHA") and Drug Enforcement Administration ("DEA") in order to prescribe or administer buprenorphine to individuals receiving treatment for opioid use disorder. Section 1262 of the federal Consolidated Appropriations Act, Pub. L. No. 117-328 (2022) removed DATA 2000 waiver requirements, and any provider who has current DEA registration which includes Schedule III authority may prescribe buprenorphine for opioid use disorder in their practice if permitted by state law. Section 961.38 (3) and (4g), Stats., authorize dispensing Schedule III drugs when prescribed for medical treatment.

As currently written, an outpatient mental health clinic certified under ch. DHS 35 seeking to provide treatment for co-occurring substance use disorder for any patient must also obtain a separate certification under s. DHS 75.50 for outpatient substance use treatment. This creates a burden on providers, who must either obtain another certification or refer the patient to a separate provider, and a burden on individuals who need to have two behavioral health providers and can contribute to individuals not receiving needed substance use treatment.

Sections DHS 75. 51 and 75.52 govern intensive outpatient treatment and day treatment/partial hospitalization treatment services, respectively. As currently written, these services cover treatment services for individuals with substance use disorder. These certifications do not permit these services to provide integrated services.

Section DHS 75.56 restricts integrated behavioral health stabilization services to residential settings. The restriction to residential treatment in s. DHS 75.56 means that services cannot be provided community-based setting for less than 24 hours a day. In contrast, s. DHS 75.57 permits residential withdrawal management services in community-based settings.

Section DHS 75.24 (1) (a) 3., general service operations, require service providers to assess each patient's suicide risk, and s. 75.19 (4) (c) 1. requires that a service assess and manage suicidal individuals. However, s. DHS 75.56 (3) (b) excludes individuals with "a recent suicide attempt or ongoing suicidal ideation combined with a continued threat or plan to act" from admission to a stabilization service. This restriction inadvertently limits access to care for individuals as certified programs are required to be equipped to assess a person's level of suicide risk and determine if the facility and program are equipped to ensure for an individual's safety.

Section DHS 75.24 (9) (a) 2., establishes policy and procedure standards for intake that require certified agencies to obtain information concerning communicable illnesses, such as sexually transmitted infections, hepatitis, tuberculosis, and HIV, and refer patients with communicable illness for treatment when appropriate. Sections DHS 75.59 (6) (e) 1., DHS 75.59 (19) (c), and DHS 75.60 (7) (a) 10. and 11. currently require testing for hepatitis.

Section DHS 101, DHS 105, and DHS 107 do not currently include policies which govern intensive outpatient behavioral health services. The proposed changes would create integrated intensive outpatient treatment, which is a level of care between outpatient and day treatment services for both SUD and mental health services. In addition, these chapters need to be updated to included integrated day treatment as changes outlined in s. DHS 75.52. The proposed changes would allow DHS 75 certified providers to offer and gain reimbursement for both SUD and mental health day treatment services.

3. Policies proposed to be included in the rule

First, the proposed rules seek to amend ss. DHS 75.60 (4) (b) and (8) (a) to remove outdated references to DATA 2000 waivers. This will achieve consistency with Section 1262 of the federal Consolidated Appropriations Act, Pub. L. No. 117-328 (2022), as SAMHSA and the DEA no longer require waivers in order for a service to prescribe buprenorphine.

Second, the proposed rules seek to amend ss. DHS 75.49 and DHS 75.50 by adding an applicability section that includes an exemption to ch. DHS 75 certification requirements for ch. DHS 35 certified outpatient mental health clinics and licensed rural health centers. This exemption from DHS 75 certification would allow these clinics to provide substance use disorder treatment services when co-occurring with the provision of mental health services. In addition, an added exclusion in applicability would be put in place for rural health clinics. Allowing ch. DHS 35 certified clinics to serve individuals with a substance use disorder will reduce waitlists, increase access to care—which can reduce the incidence of overdose and death—and promote the best practice of integrated care to treat co-occurring mental health and substance use disorders.

Third, the proposed rules seek to amend ss. DHS 75. 51 and 75.52, by adding language that allows intensive outpatient treatment services and day treatment or partial hospitalization treatment services to provide integrated services that are consistent with the proposed applicability exceptions in s. DHS 75.50, which would allow for all of the following:

— Providing integrated treatment for both mental health and substance use needs.
— Embracing evidence-based practices in treatment.
— Offering treatment to a level of intensity based on consumer needs.

— Streamlining rules to improve quality of care and ease access to treatment services and providing greater flexibility to providers for adopting best-practices in community mental health treatment.
— Maximizing a limited behavioral health workforce and improving member access to care.

Fourth, the proposed rules seek to amend provisions to allow for community-based treatment provided for less than 24 hours a day within DHS 75.56 stabilization services. This will increase access to the service and achieve consistency with the intent behind the creation of this service. Updates to Table DHS 75.48 are necessary to reflect these changes as well.

Fifth, the proposed rules seek to remove an exclusion under the s. DHS 75.56 adult residential integrated behavioral health stabilization service which prohibits admission of individuals with current or recent suicidal ideation. In accordance with ss. DHS 75.24 (1) (a) 3. and 75.19 (4) (c) 1., programs certified under s. DHS 75.56 are equipped to assess a person's level of suicide risk and determine if the facility and program are equipped to ensure for an individual's safety. Removing this restriction will increase access to this needed level of care.

Sixth, the proposed rules seek to amend s. DHS 75.48 (2) (m) and (n) and (o) to allow a treatment plan to be waived under a DHS 75.56 service if an individual resides at the facility for less than 48 hours. This is justified because a stay of this length likely will not have had enough time to develop a treatment plan for the individual.

Seventh, the proposed rules seek to remove hepatitis testing requirements from opioid treatment programs and office based opioid treatment service standards under ss. DHS 75.59 (6) (e) 1., DHS 75.59 (19) (c), and DHS 75.60 (7) (a) 10. and 11. The removal of the testing and management plan requirements specific to hepatitis is based on several factors:

— Testing is expensive for providers, insurers, and individuals in need of care.
— It is not an evidence-based practice to test everyone. CDC guidance provides that best practice to screen and then refer for testing when indicated (CDC guidance).
— Local public health departments are not equipped to respond to every positive screen and develop a management plan.

Eighth, the proposed rules seek to allow the MA program to certify and reimburse for services outlined in s. DHS 75.51, which establishes intensive outpatient treatment in mental health, SUD, and integrated care.

Ninth, the proposed rules seek to create s. DHS 105.235 and amend s. DHS 107.13 to clarify that qualified treatment trainees (QTTs) and staff who are qualified to provide and be reimbursed for substance use disorder (SUD) or alcohol and other drug abuse (AODA) treatment and what this service will entail.

Finally, the proposed rules seek to make day treatment services as an integrated certification in s. DHS 75.52. The MA program seeks to update its own chapters on day treatment in ss. DHS 105.24, DHS 105.25, and DHS 107.13 to better associate with new standards of care and allow for DHS 75 certified providers to offer and be reimbursed for both SUD and mental health integrated day treatment services.

4. Analysis of policy alternative

There are no alternatives to the proposed rulemaking to amend ss. DHS 75.60 (4) (b) and (8) (a). If the Data 2000X Waiver language is not removed, it will be impossible for providers to meet the requirements in DHS 75 which would typically lead to citations from the Division of Quality Assurance.

All clinics providing substance use disorder treatment must currently be certified under ch. DHS 75. If an exemption is not added to ch. DHS 75 for ch. DHS 35 certified providers treating co-occurring substance use

disorder treatment, those clinics will either not be to provide integrated treatment or need to go through the process of obtaining DHS 75 certification. The Department has already learned that some providers have simply chosen to not serve individuals with co-occurring substance use disorders.

The Department could potentially create levels of care specific to mental health needs outside of ch. DHS 75. This alternative is not feasible because mental health and substance use services are often co-occurring, and such actions would result in incongruency between what is available for treatment services, and this will further cause strain on the behavioral health workforce.

There are no alternatives to amending s. DHS 75.56 to permit community-based care. "Residential" is undefined in that section of the rule, and the plain meaning of the term conflicts with providing service in a community-based setting for less that 24 hours. Crisis stabilization is designed for short-term, acute stays that may vary in length from a few hours to several days. Once the crisis is resolved, an individual should be discharged to less restrictive care as soon as possible.

There are no alternatives to amending s. DHS 75.56 regarding excluding patients with recent suicide attempts or ideation. As written, the rule conflicts with other general provisions in s. DHS 75.19, and access to stabilization services is essential for an individual in crisis.

There are no alternatives to removing mandatory hepatitis testing requirements. If not removed, providers will continue to test for hepatitis or be cited by the Division of Quality Assurance for not completing the testing. Public health departments will struggle to manage the volume of screening referrals with corresponding management plans.

There are no reasonable policy alternatives for MA reimbursement of intensive outpatient level of care. The proposed changes would create a needed level of care that provides congruency between mental health and substance use services. If coverage is not added for this level of care, there is potential for MA members to receive the inappropriate level of care which could result in poor health outcomes.

There are no reasonable alternatives for the MA program to update integrated day treatment services. The proposed changes would create a new integrated level of care that provides congruency between mental health and substance use services. If coverage is not adjusted for this integrated care, there is potential for MA members to seek out multiple disjointed treatment services which could result in poor health outcomes.

5. Statutory authority for the rule

a. Explanation of authority to promulgate the proposed rule

The Department's authority to promulgate the proposed rules is provided in ss. 49.45 (2) (a) 11. a. and b. and (30e) (b), 51.04, 51.42 (7) (b) 1., 8., and 11., 51.421 (3) (a) and (c), 51.4224 (2), 51.45 (3) (a), (8) (a), and (9), and 227.11 (2), and 227.24, Stats.

b. Statute/s that authorize/s the promulgation of the proposed rule

The following statutory sections authorize the Department to promulgate rules for certifying emergency health service programs, outpatient mental health clinics, community-based psychosocial service and rehabilitation programs, community mental health and developmental disability programs, and community support programs for persons with chronic mental illness:

Section 49.45 (2) (a) 11. a. and b., Stats.:
(2) DUTIES.

(a) The department shall:

. . . 11. a. Establish criteria for certification of providers of medical assistance and, except as provided in par. (b) 6m. and s. 49.48, and subject to par. (b) 7. and 8., certify providers who meet the criteria.

b. Promulgate rules to implement this subdivision.

Section 49.45 (30e) (b), Stats.:

(30e) COMMUNITY-BASED PSYCHOSOCIAL SERVICE PROGRAMS.

(b) *Rules*. The Rules. The department shall promulgate rules regarding all of the following:

1. Standards for determining whether an individual is eligible under par. (a) 3.

2. The scope of psychosocial services that may be provided under s. 49.46 (2) (b) 6. Lm.

3. Requirements for certification of community-based psychosocial service programs.

4. Any other conditions for coverage of community-based psychosocial services under the Medical Assistance Program.

Section 51.04, Stats.:

Treatment facility certification. Except as provided in s. 51.032, any treatment facility may apply to the department for certification of the facility for the receipt of funds for services provided as a benefit to a medical assistance recipient under s. 49.46 (2) (b) 6. f. or 49.471 (11) (k) or to a community aids funding recipient under s. 51.423 (2) or provided as mandated coverage under s. 632.89. The department shall annually charge a fee for each certification.

Section 51.42 (7) (b) 1. , 8. 11., Stats.:

(7) DUTIES OF THE DEPARTMENT OF HEALTH SERVICES.

(b) The department shall promulgate rules which do all of the following:

1. Govern the administrative structure deemed necessary to administer community mental health, developmental disabilities, alcoholism and drug abuse services.

. . . 8. Prescribe such other standards and requirements as may be necessary to carry out the purposes of this section.

. . . 11. Prescribe requirements for certification of community mental health programs, except as provided in s. 51.032, including all of the following:

a. A requirement that, as part of the certification process, community mental health programs must demonstrate that their staff have knowledge of laws, regulations and standards of practice which apply to the program and its clients.

b. A requirement that, when conducting certifications, certification staff must use a random selection process in reviewing client records.

c. A requirement that certification staff conduct client interviews as part of the certification process.

d. A requirement that certification staff provide certification results to the community mental health program reviewed, to subunits within the department responsible for community mental health program monitoring and to the county department under this section in which the community mental health program is located upon completion of certification.

This section provides that the Department shall promulgate rules to prescribe requirements for certification of community mental health programs.

Section 51.421 (3) (a) and (c), Stats.:

(3) DEPARTMENTAL DUTIES. The department shall:

(a) Promulgate rules establishing standards for the certified provision of community support programs by county departments under s. 51.42, except as provided in s. 51.032. The department shall establish standards that ensure that providers of services meet federal standards for certification of providers of community

support program services under the medical assistance program, 42 USC 1396 to 1397e. The department shall develop the standards in consultation with representatives of county departments under s. 51.42, elected county officials and consumer advocates.

. . . (c) Monitor the establishment and the continuing operation of community support programs and ensure that community support programs comply with the standards promulgated by rule. The department shall ensure that the persons monitoring community support programs to determine compliance with the standards are persons who are knowledgeable about treatment programs for persons with serious and persistent mental illness.

Section 51.4224 (2), Stats.:

(2) **Duration of certification.** The department shall issue a certification for an eligible opioid treatment system, as determined by the department, that remains in effect for 3 years unless suspended or revoked and coincides with the federal government certification period.

Section 51.45 (3) (a), Stats.:

(3) POWERS OF DEPARTMENT. To implement this section, the department may:

(a) Plan, establish and maintain treatment programs as necessary or desirable.

Section 51.45 (8) (a) to (e), Stats:

(8) STANDARDS FOR PUBLIC AND PRIVATE TREATMENT FACILITIES; ENFORCEMENT PROCEDURES.

(a) The department shall establish minimum standards for approved treatment facilities that must be met for a treatment facility to be approved as a public or private treatment facility, except as provided in s. 51.032, and fix the fees to be charged by the department for the required inspections. The standards may concern only the health standards to be met and standards of treatment to be afforded patients and shall distinguish between facilities rendering different modes of treatment. In setting standards, the department shall consider the residents' needs and abilities, the services to be provided by the facility, and the relationship between the physical structure and the objectives of the program. Nothing in this subsection shall prevent county departments from establishing reasonable higher standards.(b) The department periodically shall make unannounced inspections of approved public and private treatment facilities at reasonable times and in a reasonable manner.

(c) Approval of a facility must be secured under this section before application for a grant-in-aid for such facility under s. 51.423 or before treatment in any facility is rendered to patients.

(d) Each approved public and private treatment facility shall file with the department on request, data, statistics, schedules and information the department reasonably requires, including any data or information specified under s. 46.973 (2m). An approved public or private treatment facility that without good cause fails to furnish any data, statistics, schedules or information as requested, or files fraudulent returns thereof, shall be removed from the list of approved treatment facilities.

(e) The department, after notice and hearing, may under this subsection suspend, revoke, limit, or restrict an approval, or refuse to grant an approval, for failure to meet its standards.

Section 51.45 (9), Stats:

(9) ACCEPTANCE FOR TREATMENT; RULES. The secretary shall promulgate rules for acceptance of persons into the treatment program, considering available treatment resources and facilities, for the purpose of early and effective treatment of alcoholics, persons who are drug dependent, and intoxicated persons. In promulgating the rules the secretary shall be guided by the following standards:

(a) If possible a patient shall be treated on a voluntary rather than an involuntary basis.

(b) A patient shall be initially assigned or transferred to outpatient or intermediate treatment, unless the patient is found to require inpatient treatment.

(c) No person may be denied treatment solely because the person has withdrawn from treatment against medical advice on a prior occasion or because the person has relapsed after earlier treatment.
(d) An individualized treatment plan shall be prepared and maintained on a current basis for each patient.
(e) Provision shall be made for a continuum of coordinated treatment services, so that a person who leaves a facility or a form of treatment will have available and utilize other appropriate treatment.

The following statutory sections explain the Department's general authority to promulgate permanent and emergency rules:

Section 227.11 (2), Stats.:
(2) Rulemaking authority is expressly conferred on an agency as follows:
(a) Each agency may promulgate rules interpreting the provisions of any statute enforced or administered by the agency, if the agency considers it necessary to effectuate the purpose of the statute, but a rule is not valid if the rule exceeds the bounds of correct interpretation. All of the following apply to the promulgation of a rule interpreting the provisions of a statute enforced or administered by an agency:
1. A statutory or nonstatutory provision containing a statement or declaration of legislative intent, purpose, findings, or policy does not confer rule-making authority on the agency or augment the agency's rule-making authority beyond the rule-making authority that is explicitly conferred on the agency by the legislature.
2. A statutory provision describing the agency's general powers or duties does not confer rule-making authority on the agency or augment the agency's rule-making authority beyond the rule-making authority that is explicitly conferred on the agency by the legislature.
3. A statutory provision containing a specific standard, requirement, or threshold does not confer on the agency the authority to promulgate, enforce, or administer a rule that contains a standard, requirement, or threshold that is more restrictive than the standard, requirement, or threshold contained in the statutory provision.

Section 227.24 (1) (a), Stats.:
(1) PROMULGATION.
(a) An agency may, except as provided in s. 227.136 (1), promulgate a rule as an emergency rule without complying with the notice, hearing, and publication requirements under this chapter if preservation of the public peace, health, safety, or welfare necessitates putting the rule into effect prior to the time it would take effect if the agency complied with the procedures.

c. Statute/s or rule/s that will affect the proposed rule or be affected by it

Chapter DHS 35, relating to outpatient mental health clinics.
The Consolidated Appropriations Act, Public Law No. 117-328 s. 1262 (2022).

6. Estimates of the amount of time that state employees will spend to develop the rule and other necessary resources

The estimated time for state employees to develop the rule is 1,040 hours.

7. Description of all of the entities that may be affected by the rule, including any local governmental units, businesses, economic sectors, or public utility ratepayers who may reasonably be anticipated to be affected by the rule

DHS 35 certified outpatient mental health clinics
DHS 75.51 intensive outpatient treatment services

DHS 75.52 day treatment or partial hospitalization treatment services
DHS 75.56 adult residential integrated behavioral health stabilization services
DHS 75.59 opioid treatment programs
DHS 75.60 office based opioid treatment service programs
Rural health clinics
Residential treatment services
Members who access substance use disorder treatment services
Substance use disorder professionals
County and tribal agencies
The Department

8. Summary and preliminary comparison of any existing or proposed federal regulation that is intended to address the activities to be regulated by the rule

A summary of the relevant provisions in the federal Consolidated Appropriations Act, which removed DATA 2000 waiver requirements for prescribing buprenorphine, is available at https://www.samhsa.gov/medications-substance-use-disorders/removal-data-waiver-requirement.

9. Anticipated economic impact, locally or statewide

The proposed rule is not anticipated to have an economic impact. These changes would create fiscal savings for providers and could create fiscal savings for individuals.

10. Agency contacts

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