

Clearinghouse Rule 19-021

**WISCONSIN DEPARTMENT OF HEALTH SERVICES
PROPOSED ORDER TO ADOPT PERMANENT AND EMERGENCY RULES**

The Wisconsin Department of Health Services proposes an order to repeal s. DHS 75.15 (9) (a), relating to community substance abuse service standards.

FINDING OF EMERGENCY

Wisconsin is in the midst of a growing crisis related to misuse of opioids. There is an urgent need to address this crisis by repealing s. DHS 75.15 (9) (a), a rule provision that limits the type of entities that may be certified to provide substance abuse prevention, intervention or treatment services in the state. Preservation of the public peace, health, safety, and welfare necessitates repealing this restriction prior to the time it would take to promulgate a permanent rule.

RULE SUMMARY

Statute interpreted

Section 51.42 (7) (b), Stats.

Statutory authority

The department has been granted explicit statutory authority by the Legislature in ss. 51.42 (7) (b) and 227.11 (2) (a), Stats. to promulgate the proposed rules. Furthermore, 2017 Wisconsin Executive Order 228, Section 4 (a) requires the department to further revise ch. DHS 75 to simplify and streamline regulation of other health care and services providers to ease access to services.

Explanation of agency authority

The department's authority to promulgate rules is as follows:

Section 51.42 (7) (b), Stats., states:

- (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.
 - 2. Establish uniform cost record-keeping requirements.
 - 3. Prescribe standards for qualifications and salaries of personnel.
 - 4. Prescribe standards for quality of professional services.
 - 5. Prescribe requirements for in-service and educational leave programs for personnel.
 - 6. Prescribe standards for establishing patient fee schedules.
 - 7. Govern eligibility of patients to the end that no person is denied service on the basis of age, race, color, creed, location or inability to pay.
 - 7m. Define "first priority for services" under and otherwise implement sub. (3) (ar) 4m.
 - 8. Prescribe such other standards and requirements as may be necessary to carry out the purposes of this section.
 - 9. Promulgate rules establishing medication procedures to be used in the delivery of mental health services.
 - 10. Establish criteria for the level of scrutiny for evaluation of community mental health programs.
 - 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.

Section 227.11 (2) (a), Stats., states:

- (2) Rule-making 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.

2017 Wisconsin Executive Order 228, Section 4 (a) states:

The Wisconsin Department of Health Services shall: (a) improve Wisconsin's community substance abuse service standards to require all state-certified AODA clinics to have Naloxone on-site to administer in the event of an overdose. The Department should revise DHS Rule 75 to grant the state's opioid treatment authority greater discretion to require certified clinics to embrace evidence-based practices to treatment. The Department may further revise DHS Rule 75 to simplify and streamline regulation of other health care and service providers to ease access to services.

Related statute or rule

Section 51.4224 (1) and (2), Stats., states:

- (1) **DEFINITIONS.** In this section:
 - (a) "Narcotic treatment service for opiate addiction" is an opioid treatment system that includes a physician who administers or dispenses a narcotic drug to a narcotic addict for treatment or detoxification treatment with a comprehensive range of medical and rehabilitation services; that is approved by the state methadone authority and the designated federal government's regulatory authority; and that is registered with the U.S. drug enforcement administration to use a narcotic drug for treatment of a narcotic addiction.
 - (b) "Opioid treatment system" means a structured delivery system for providing substance abuse prevention, intervention, or treatment services and meets all of the following criteria:
 1. The system receives funds through the state under this chapter.

2. The system is approved by the state methadone authority.

(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.

(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.

Plain language analysis

Section DHS 75.15 (9) (a) prohibits entities that provide substance abuse prevention, intervention or treatment-related narcotic services --referred to as Opiate Treatment Providers (OTPs) under federal law-- from also providing medical services not directly related to narcotic treatment. Repealing this provision will permit a wider array of medical providers to become certified as OTPs, thus addressing the urgent need to address the current, unmet need for medication-assisted treatment to individuals with opioid use disorders throughout geographic regions of Wisconsin.

Summary of, and comparison with, existing or proposed federal regulations

21 C.F.R. Section 291 and 42 C.F.R Section 8 -- medical providers may seek federal certification as an Opiate Treatment Program (OTP).

January 2015 Federal Guidelines for Opioid Treatment Programs, Substance Abuse and Mental Health Services Administration, page 43, states, "It is highly recommended, but not required, that OTPs provide basic primary care onsite. OTP physicians can prescribe medication as appropriate for co-occurring medical and psychiatric disorders."

<https://store.samhsa.gov/shin/content/PEP15-FEDGUIDEOTP/PEP15-FEDGUIDEOTP.pdf>

Comparison with rules in adjacent states

Illinois:

Section 2060.413 of the Illinois Administrative Code governs medical services. Part 2060 of the Administrative Code addresses alcoholism and substance abuse treatment and intervention licenses. Subsection 2060.413 (h) (1) states that any treatment service that uses methadone or LAAM for the treatment of opioid addiction shall comply with the provisions of 21 C.F.R § 291.505. Subsection 2060.413 (h) (3) states that organizations shall obtain prior written approval from the state department of human services for exceptions as referenced in 21 C.F.R § 505 relative to more than a three day supply of take-home medication and shall utilize the Department's Schedule H when requesting such exceptions.

Section 2060.413, subs (h) (1) and (h) (3), Illinois Administrative Code.

Iowa:

Iowa does not appear to have an administrative rule addressing whether entities that provide treatment-related narcotic services can also provide medical services not directly related to narcotic treatment.

Michigan:

Michigan does not appear to have an administrative rule addressing whether entities that provide treatment-related narcotic services can also provide medical services not directly related to narcotic treatment.

Minnesota:

Section 245G.08 within Chapter 245G (Chemical Dependency Licensed Treatment Facilities) of Minnesota's statutes addresses medical services. Subdivision 3, Standing

order protocol, states that a health care services license holder that maintains a supply of naloxone available for emergency treatment of opioid overdose must have a written standing order protocol by a physical licensed under chapter 147 of the state statutes, that permits license holder to maintain a supply of naloxone on site. Subdivision 4, Consultation services, states that a license holder must have access to and document the availability of a licensed mental health professional to provide diagnostic assessment and treatment planning assistance. Under Subdivision 5, a license holder must meet the requirements in this subdivision if a service provided includes the administration of medication.

245G.08, Subd (3), (4), and (5), 2018 Minnesota Statutes

Summary of factual data and analytical methodologies

The proposed revision is intended to permit a wider array of medical providers to become certified as Opiate Treatment Programs (OTPs). There is currently a significant need for OTPs in the northern and western regions of the State. A map of the current OTPs and additional information is available at <https://www.dhs.wisconsin.gov/opioids/find-treatment.htm>.

Analysis and supporting documents used to determine effect on small business

None. The proposed rules do not impact small businesses.

Effect on small business

The proposed rule is anticipated to have no economic impact in terms of costs imposed on narcotic treatment and other substance use disorder service providers. This rule is expected to create business opportunities for additional treatment providers.

Agency contact person

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Statement on quality of agency data

The department did not rely on data in developing the proposed rule. The proposed revision is intended to permit a wider array of medical providers to become certified as OTPs.

Place where comments are to be submitted and deadline for submission

Comments may be submitted to the agency contact person that is listed above until the deadline given in the upcoming notice of public hearing. The notice of public hearing and deadline for submitting comments will be published in the Wisconsin Administrative Register and to the department's website, at <https://www.dhs.wisconsin.gov/rules/permanent.htm>. Comments may also be submitted through the Wisconsin Administrative Rules Website, at: <https://docs.legis.wisconsin.gov/code/chr/active>.

RULE TEXT

SECTION 1. DHS 75.15 (9) (a) is repealed.

SECTION 2. EFFECTIVE DATE: This rule shall take effect on the first day of the month following publication in the Wisconsin administrative register, as provided in § 227.22 (2), Stats.