

This statement of scope was approved by the governor on April 27, 2018

STATEMENT OF SCOPE
DEPARTMENT OF HEALTH SERVICES

Rule No.: Section DHS 75.15 (9) (a)

Relating to: Community Substance Abuse Service Standards

Rule Type: Permanent and Emergency

Type of Statement of Scope: Original

1. Finding/nature of emergency (Emergency Rule only):

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.

2. Detailed description of the objective of the proposed rule:

The objective is to create both an emergency and permanent rule to repeal s. DHS 75.15 (9) (a). This provision currently prohibits entities that provide substance abuse prevention, intervention or treatment services¹—referred to as Opiate Treatment Providers (OTPs) under federal law— from also providing medical services not directly related to narcotic treatment. Repealing s. DHS 75.15 (9) (a) will permit a wider array of medical providers to become certified as OTPs.

¹These entities are currently referred to as *systems* in ch. DHS 75, and have also been referred to as *narcotic treatment service agencies*, or *programs*.

3. Description of the existing policies relevant to the rule, new policies proposed to be included in the rule, and an analysis of policy alternatives:

Policy Problem

Wisconsin data from the National Survey on Drug Use and Health shows that 4.3% of Wisconsin adults (or 163,000 adults) report using heroin or another opioid (for nonmedical purposes) in 2016. Among young Wisconsin adults age 18-25, the rate of past year use of opioids is 11% (or 68,600 persons).² Between the years 2000-2012, Wisconsin experienced a 333% increase in deaths involving prescription opioids. According to the Wisconsin Interactive Statistics on Health (WISH) data query system, in 2016 there were 827 opioid overdose deaths in Wisconsin, a 34.7% increase over the prior year with a total of 614 deaths.³ In 2004, 36 Wisconsin counties reported no opioid-related deaths, while by 2015 that number dropped more than 60% to only 14 Wisconsin counties. These statistics show that Wisconsin is in the midst of a growing crisis related to opioids misuse.

² <https://www.samhsa.gov/data/sites/default/files/NSDUHsaeTotal2016/NSDUHsaeTotals2016.pdf> (Table 11)

³ <https://www.dhs.wisconsin.gov/wish/opioid/index.htm>

The prevalence of prescription drug misuse has also contributed to a rise in substance use disorder treatment admissions for prescription drug dependence and addiction. Between the years 2008-2011, the number of treatment admissions for opioids other than heroin grew 43.9%. Moreover, the number of persons receiving county-authorized services for any opiate drug abuse increased 132%, from 2,096 persons in 2005 to 4,861 in 2015. These various rate increases demonstrate the growing need for treatment resources to treat opioid use disorders (OUDs).

There are currently a total of 18 OTPs that are certified under s. DHS 75.15; all of them are located in the southern half of the state. This leaves large parts of the state without adequate access to these critical treatment services. In 2016, those 18 clinics served 8,160 patients who received medication-assisted treatment. However, recent data also shows that the need for medication-assisted treatment far exceeds the current capacity of these 18 providers. Thus, there is an urgent need to address this crisis, by expanding the number and geographic distribution of OTPs that provide evidence-based treatment options to individuals with significant OUDs

New Policy

The Department proposes to repeal s. DHS 75.15 (9) (a). This will permit a wider array of medical providers to become certified under ch. DHS 75 as OTPs.

Policy Alternatives

1. The Department could repeal s. DHS 75.15 (9) (a) during a more comprehensive revision of ch. DHS 75. However, the complexity and the scope of this comprehensive revision will require greater time and resources to complete, leaving the current opioid crisis unaddressed.
2. The Department could continue to promote awareness of the need for additional providers to offer substance abuse prevention, intervention or treatment services within the existing ch. DHS 75 framework. However, s. DHS 75.15 (9) (a) would continue to present a barrier for many providers that seek certification, again leaving the current opioid crisis unaddressed.

4. Detailed explanation of statutory authority for the rule (including the statutory citation and language):

The proposed rulemaking is explicitly authorized by the Legislature in the following statutory provisions.

Section 51.42 (7) (b), Wis. Stats., reads:

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.
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.

2017 Wisconsin Executive Order 228, Section 4 (a), reads in part:

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.

Section 227.11 (2) (a), Wis. Stats., reads:

(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 non-statutory 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 in the statutory provision.

5. Estimate of amount of time that state employees will spend developing the rule and of other resources necessary to develop the rule :

The Department estimates that staff will devote approximately 75 hours to promulgate the rule. This includes the time required for research and analysis, drafting the rule, and complying with Wisconsin's rule promulgation procedure.

6. List with description of all entities that may be affected by the proposed rule :

Entities that may be affected by the proposed rule include:

- (a) Consumers of substance abuse prevention, intervention or treatment services, and their families.
- (b) Wisconsin county and tribal agencies providing substance abuse prevention, intervention or treatment services.
- (c) Treatment providers that receive funding under ch. 51, Wis. Stats., and that are governed by ch. DHS 75.

- (d) Other professionals involved in substance abuse prevention, intervention, treatment or coordination services.
- (e) Organizations that represent consumers of substance abuse prevention, intervention or treatment services.
- (f) Existing, certified providers of substance abuse prevention, intervention or treatment services under ch. DHS 75.
- (g) Healthcare insurers and healthcare provider organizations.

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

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

The January 2015 Federal Guidelines for Opioid Treatment Programs, issued by the Substance Abuse and Mental Health Services Administration, states on page 43, “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.”⁴

⁴ <https://store.samhsa.gov/shin/content/PEP15-FEDGUIDEOTP/PEP15-FEDGUIDEOTP.pdf>

8. Anticipated economic impact of implementing the rule :

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 substance use disorder and narcotic treatment providers.

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