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Department of Health Services
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Comments submitted via email

RE: Invitation to comment on CR 20-047 – DHS 75 - relating to community substance abuse service standards

Dear Ms. Lake-Cismesia:

The Department of Health Services invited stakeholders to comment on the Department's proposed repeal and recreation of DHS 75 pursuant to Clearinghouse Rule CR 20-047. The Wisconsin Hospital Association (WHA) appreciates that invitation. WHA's membership includes over 140 member hospitals and integrated health systems.

WHA's membership includes health care providers who treat a range of substance use disorders in hospital, residential, and clinic settings, and have a direct interest in the proposed rule. Because of the broad array of substance use disorder services provided by WHA member health systems, WHA's members have an interest in multiple sections and services regulated in this 97-page rule. These comments are in addition to the comments provided by WHA in a comment letter on the economic impact of the proposed rule and in comments during and before the DHS 75 advisory committee process.

Overall, while the draft proposed rule updates DHS 75 to incorporate modern terminology and does remove some out-of-date regulatory prescription, we believe that the draft proposed rule needs significant further review and changes prior to becoming law. In particular, we are concerned that the significant over-prescription in the proposed rule will make access to care more difficult – the opposite outcome of the primary intent of this rulemaking effort.

Providers have repeatedly identified overregulation of the provision of substance use disorder services as directly impacting the accessibility of those services.

Expanding access to treatment for substance use disorder throughout Wisconsin has been identified as a significant need in multiple reports, recommendations, and executive actions developed in multiple state-level task forces and commissions since 2016. WHA and WHA members have been engaged in multiple efforts to expand access to substance use disorder services, including The Governor's Task Force on Opioid Abuse, and have provided input into the development of the proposed DHS 75 through its listening sessions, the DHS 75 Advisory Group, and comments during the economic impact analysis stage of the rulemaking process.

Governor's Opioid Task Force

In 2016, Joan Coffman, then President and CEO of HSHS St. Joseph's Hospital in Chippewa Falls, served on the Governor's Task Force on Opioid Abuse as a leader of an organization providing outpatient, inpatient, and residential substance use disorder services, and provided the following written testimony to the Task Force identifying overregulation as a significant impact on accessibility of substance use disorder services:

> "Wisconsin specially regulates AODA treatment facilities and providers through administrative rules such as DHS 75. For AODA providers, these regulations are in addition to federal regulations, including DEA, FDA, and CMS regulations, as well as other generally applicable state licensure regulations governing hospitals, community-based residential facilities, group homes, and individually licensed practitioners such as physicians, nurses, and therapists. Increasingly, WHA has heard from AODA providers concerned that Wisconsin's special AODA treatment rules are not keeping up with changes in care delivery, including integrated primary care delivery models, and that the rules are can create costly and unnecessary burdens that make it difficult – and in some cases economically infeasible – to expand AODA treatment services."

Others echoed the impact of regulation on access to care, particularly regarding efforts to expand the number of buprenorphine prescribers in Wisconsin. Ultimately, one recommended strategy and outcome of the Governor's Task Force on Opioid Abuse was 2017 Executive Order 228, which directed that DHS "revise DHS Rule 75 to simplify and streamline regulation of other health care and service providers to ease access to services." That Executive Order is identified in the rule's scope statement as the impetus for this proposed rule.

DHS listening sessions

Following the issuance of the scope statement for the proposed rewrite of DHS 75, WHA members and others participated in multiple listening sessions held by the Department to help inform DHS's development of the proposed rule.

The May 2019 listening sessions were attended by health system substance abuse providers from HSHS/Libertas, Marshfield Clinic Health System, Gundersen Health System, and Mayo Clinic Health System as well as several local agency substance abuse providers. As reported in WHA's May 28, 2019 newsletter, common themes of the comments provided included:

- The substance abuse treatment field has "professionalized" with professional education and licenses since these rules were first created. Because DHS 75 has not evolved with that professionalization, providers must navigate unnecessary and overlapping regulatory prescriptiveness and particularity.
- The DHS 75 clinical supervision requirements are outdated and often inconsistent with a modern "professionalized" substance abuse treatment delivery model.
- The DHS 75 rules frequently require multiple signatures and reviews that create paperwork burden but no meaningful benefit for patient care.
- Separate treatment service-type silos are creating unnecessary barriers to service model flexibility and integration.
- **"It's highly overregulated. All of these nitpicky rules reflect what was once an emerging field,"** said one local agency provider summarizing various comments from others. "Providers don't last if they are not doing a good job."

The June 2019 listening sessions were attended by health system substance abuse providers from Aurora Health Care, ProHealth Care, and Rogers Behavioral Health, as well as several local agency substance abuse providers. As reported in WHA's June 25, 2019 newsletter, common themes of the comments provided included:

- The DHS 75 clinical supervision requirements are outdated and often inconsistent with a modern licensed and professionalized substance abuse treatment delivery model.

- The DHS 75 rules frequently require multiple signatures and reviews that create paperwork burden but no meaningful benefit for patient care.
- Separate treatment service-type silos are creating unnecessary barriers to service model flexibility and integration.
- The lengthy time period to get certified by DHS to provide substance abuse services and different interpretations from surveyors is a frustration.
- Current rules are inconsistent with modern technology, including telemedicine and electronic health records.
- "Medicaid telehealth regulations really handcuff us as to what technology we are able to utilize day to day," said one provider. "We actually decided to end our telehealth certification after we got it due to all of the additional hoops," said another provider.
- Providers also universally expressed frustration that the rule regulates as if Wisconsin doesn't have separate licensing requirements for substance abuse treatment professionals.
- "The rule is full of language that doesn't recognize licensed professionals," explained a provider. **"The rule has requirements that are not in place for any other diagnosis that licensed professionals treat."**

The July 2019 listening sessions were attended by 40 behavioral health providers. As reported in WHA's July 23, 2019 newsletter, common themes of the comments provided included:

- The DHS 75 clinical supervision requirements are outdated and often inconsistent with a modern licensed and professionalized substance abuse treatment delivery model.
- The DHS 75 rules frequently require multiple signatures, documentation and reviews that create paperwork burden, but no meaningful benefit for patient care.
- Separate treatment service-type silos are creating unnecessary barriers to person-centered health care and service model flexibility and integration.
- Current rules are inconsistent with modern electronic health records technology.
- "**Be cautious about making DHS 75 too prescriptive**," said Michael Wapoose, Director of Behavioral Health, Quartz Health Plan. "Treatment should be designed to community needs. The prescriptiveness of the current role is a real problem and burden during surveys."
- Others said that current prescriptiveness and documentation requirements negatively impacts access and treatment.
- "There is lots of time spent on lots of paperwork," said one provider. "We need more time with patients. Instead, we are seeing more challenging patients, requiring more needs and more steps, many of which are not reimbursed." "Sign, sign, sign," was the way another provider described the current paperwork burden.
- Others cautioned against enshrining a particular evidence-based practice in rule and one provider asked DHS to consider the purpose of having a rule. "**The purpose of having a rule should be to ensure someone is not endangered by solely receiving a service. We need to ensure the rule allows individuals to get the number and type of services they need.**"

DHS 75 Advisory Committee

WHA participated in the DHS 75 Advisory Work Group, and WHA along with other members of the Work Group regularly raised concerns about regulatory prescriptiveness and the compliance burden of "showing your work" for regulatory requirements. Such prescriptiveness and compliance burden creates additional administrative costs to operate a program, adds to paperwork burden for clinicians that either reduces the number of patients the clinician can see or increases the clinician's overall workday, and limits innovation and flexibility among providers to provide efficient, high quality care.

Because DHS 75 covers so many different types of substance use disorder services, but at the same time intersects with professional licensing rules and other DHS rules, such as Medicaid rules, current DHS 75 is an extremely complex regulation. WHA appreciates the significant work undertaken by DHS staff in a short amount of time to recreate DHS 75, but because of the breadth of services regulated by and proposed detailed complexity of the proposed rule, comprehending the full, on-the-ground impact of the proposed rule as it was developed was inherently challenging.

To help better understand what would and would not be substantively changed in the rewrite of DHS 75, WHA requested during the DHS 75 Advisory Committee meetings that a cross walk be provided directly comparing proposed language with current rule language. WHA believes that analysis is critical for all stakeholders, particularly existing entities regulated by DHS 75, to fully understand and meaningfully comment on the practical impact of the proposed rule. Unfortunately, that cross-walk analysis was not completed, and we believe hampered the ability of the Advisory Committee and DHS to fully comprehend the proposed changes. As noted in requested "next steps" at the end of this letter, WHA again asks for DHS to develop a full cross walk of the current rule and the proposed rule to help fully inform changes to the proposed rule before it becomes law.

An objective comparison of the proposed DHS 75 to the current rule and other states' rules indicates that the rule adds significant regulatory complexity.

The full administrative costs of the proposed rule are difficult to fully and precisely quantify, but together with professional requirements regulated by the Department of Safety and Professional Services, federal Substance Abuse and Mental Health Services Administration rules and requirements, payer requirements, liability risk mitigation and other overlapping state and federal regulatory requirements and processes that also assure minimum levels of quality and safety, the requirements in proposed DHS 75 add up to not insignificant administrative and opportunity costs for health care providers. We believe that the rule on the whole still needs additional work to reduce the regulatory burden and compliance costs of DHS 75 in order to achieve the goals to expand access to substance abuse treatment throughout Wisconsin.

A basic analysis of word counts, definitions, and paragraph counts can give an indication of Wisconsin's draft proposed rule cost and burden on regulated entities. Such analysis of the draft proposed rule versus the current rule and other comparative federal and states' rules suggest that the draft proposed rule does not achieve the Executive Order direction to "*simplify and streamline* regulation" to ease access to services. Instead, the quantitative analysis below shows that the draft proposed rule is significantly longer and more detailed than the current rule, and that Wisconsin's rules were already the most detailed compared to other federal and state substance use disorder services rules.

	Word count	**Paragraph count**	**Definition count**
Draft Proposed DHS 75	41,610	2279	130
Current DHS 75	29,925	1138	99
Percent Increase	39.0%	100.3%	31.3%
Federal Opioid Treatment Program Requirements - 42 CFR Part 8[1]	15,182	447	43
Vermont[2] - Substance Use Disorder Certification Rule - Chapter 8, Subchapter 4[3]	1195	74	10
Vermont – Preferred Providers: Substance Use Disorder Treatment Standards[4]	18,462	1492	56

[1] https://www.law.cornell.edu/cfr/text/42/part-8

[2] Vermont's hub and spoke model of care was held out as a model to emulate in various Wisconsin opioid treatment reports and work groups. For that reason, it is included in this comparison of federal law and surrounding states.

[3] https://www.healthvermont.gov/sites/default/files/documents/pdf/Reg_ADAP%20Treatment%20Rule%20Clean%2012.11.19.pdf

[4] www.healthvermont.gov/sites/default/files/documents/pdf/ADAP_Preferred_Providers_SUD_Treatment_Standards_2020.pdf

Michigan – Substance Use Disorder Services Program - R. 325.1301-325.1399[5]	13,607	615	42
Minnesota – Chapter 245G. Chemical Dependency Licensed Treatment Facilities[6]	15,369	654	34
Minnesota – Chapter 2960 - Chemical Dependency Treatment Program Certification Standards[7]	4231	NA	0
Minnesota – 245.4863 – Integrated Co-occurring disorder treatment[8]	315	9	0
Illinois – Alcoholism and Substance Abuse Treatment and Intervention Licenses – Rule 2060[9]	25,637	873	70
Iowa – Chapter 155: Licensure Standards for Substance Use Disorder and Problem Gambling Treatment Programs[10]	24,043	862	89

We appreciate that the draft proposed rule does eliminate some outdated and unnecessarily prescriptive provisions that should reduce unnecessary regulatory cost. However, in many cases throughout the recreated rule, unnecessary detail and prescription remains, and in cases such as the new regulation of office-based opioid treatment, will create new compliance requirements and costs.

The new office-based opioid treatment provision first introduced after the completion of the DHS 75 Advisory Committee is contrary to goals to expand the number of buprenorphine prescribers and should be removed.

WHA has concerns about unnecessary compliance costs throughout the draft, but WHA is also particularly concerned with the new DHS 75.63 office-based opioid treatment section that was added to the draft without discussion after the third and final DHS 75 Advisory Work Group meeting. This change appears to newly regulate a vast number of office-based providers authorized to prescribe or administer buprenorphine products.

Multiple Wisconsin task forces have identified the need to encourage more physicians and prescribers to prescribe and administer buprenorphine in office-settings. Such providers are already specially regulated by federal law, and the federal DEA regulations themselves have been identified multiple times in prior opioid task forces as an added administrative barrier that has deterred more physicians and other prescribers from offering office based buprenorphine treatment.

This new regulation will create additional cost and burden on a large number of providers – the exact types of providers that multiple Wisconsin task forces the Wisconsin has been working to expand access to. Not only will this new rule

[5] https://dtmb.state.mi.us/ORRDocs/AdminCode/1888_10901_AdminCode.pdf
[6] https://mn.gov/dhs/partners-and-providers/licensing/substance-use-disorder-treatment/
[7] https://mn.gov/dhs/partners-and-providers/licensing/substance-use-disorder-treatment/
[8] https://www.revisor.mn.gov/statutes/cite/245.4863
[9] https://www.ilga.gov/commission/jcar/admincode/077/07702060sections.html
[10] https://idph.iowa.gov/substance-abuse/program-licensure

impose additional compliance costs on such existing providers, but there will be an opportunity cost to Wisconsin patients and communities as adding additional regulation will deter new providers from providing these services.

Apart from the general opposition to adding an entirely new regulatory scheme on office-based buprenorphine providers, specific elements of the new regulation are troubling in their regulatory breadth. The new regulation provides multiple concerning powers to the State Opioid Treatment Authority, including authority to create additional "required practices" without utilizing the rulemaking process, authority to conduct unscheduled compliance surveys, and authority to shut down an office-based buprenorphine provider without clear standards or procedures.

The proposed regulation also includes highly detailed and specific requirements for treatment protocols and prescriptions that substitute the medical judgment of medical providers and will inevitably become outdated as best practice treatment interventions evolve. Some provisions are already outdated. For example, although encouraging primary care physicians and advance practice nurses to become DEA buprenorphine prescribers has been widely identified as a key goal for Wisconsin – and multiple presentations have been provided regarding primary-care based medication assisted treatment successes in Wisconsin - the rule creates special, additional referral requirements for buprenorphine prescribers that are not physician addictionologists or psychiatrists.

Creating an entirely new state-based regulatory structure for office-based buprenorphine treatment is a major, and unwelcomed, addition to DHS 75, that was not discussed by the DHS 75 Advisory Work Group, was never recommended by the various task forces identifying ways to improve Wisconsin's treatment response to opioid addiction, and will negatively impact access to office-based buprenorphine treatment. The entirety of proposed DHS 75.63 should be stricken.

Other specific regulatory issues identified by WHA members.

Prior to proposed DHS 75 becoming law, WHA requests that the final rule address each of the following issues identified by WHA members and previously communicated to the Department.

- If a facility is accredited by the Joint Commission or a recognized accreditation body, a state certification survey should not be required.

- The personnel requirements in current DHS 75 are overly burdensome and require utilization of clinicians in director roles that should not require a clinical degree. There are not enough available clinicians to provide necessary services; requiring clinicians to serve in administrative roles reduces the total hours that clinicians are available to do clinical work.

- Provisions that prohibit or add barriers to the co-location or co-mingling of differing levels of care should be removed. For example, prohibitions on residential patients receiving treatment or being amongst patients in out patient settings need to be removed.

- Throughout, the regulations need to recognize that advance practice nurse prescribers (APNP) and physician assistants (PAs) may undertake roles permitted by their licensure that historically only physicians were permitted to undertake. For example, the current rules contemplate requirements that a "physician" must sign or approve certain actions under the regulations, even though an APNP or PA may be permitted under their licensure to take those steps and even have specialized training and education in behavioral health. Any treatment director requirements should also recognize the modern scope of practice and training of APNPs and PAs.

- The requirements for an evaluation plans in current DHS 75.03, particularly the requirement for measuring and gathering data on progress and outcomes, are overly prescriptive and requires information that can sometimes be very difficult to collect. This specificity should be removed.

- Inflexible maximum group counseling ratios need to be removed to ensure the ratios do not unnecessarily limit the number of patients that could be served.

- The current requirements for "placement criteria summaries" are too detailed and cumbersome. Specifically, the requirement that the name, address, phone number of the agency being referred to along with signatures of the patient and interviewer is not necessary and doesn't add to improved patient care.

- The requirements for clinical supervision are too prescriptive. The amount of detail about what needs to be covered and documented for clinical supervision doesn't add to improved patient care and puts additional burden on the provider resulting in excessive documentation, particularly when you have a large clinic. It also doesn't rely on the expertise and judgement of clinical supervisors to do their jobs effectively and efficiently. The requirement for supervision notes doesn't account for those professionals who make every effort to complete work electronically when possible. Currently, providers maintain supervision notes electronically, but during previous licensing surveys, some have been instructed to print all the notes and physically sign them.

- Detailed requirements for individualized training plans, documentation of progress and completion of staff development goals is unnecessary and cumbersome. If an organization does annual performance reviews that should meet this requirement. This requirement doesn't respect the professionalism of the counselor to work towards continuous professional development. In addition, the rules do not recognize professional licensure and certification requirements for continuing education. Meeting those separate professional licensure and certification requirements should be sufficient for staff development.

- Confusing and redundant requirements for service plans and treatment plans and recommendations should be eliminated.

- Treatment plan signature requirements are unnecessarily time consuming, confusing and not consistent with the delivery of health care in team-based care delivery settings that utilize electronic health records.

- Multiple signatures and redundant reviews need to be removed for dually credentialed mental health and substance use disorder professionals. The rule should specifically call out that if the counselor is dually credentialed they meet all the requirements for mental health professional involvement.

- The requirements for staffing notes need to be eliminated. It is difficult and time consuming for providers to try to track who frequently a patient is being seeing and then figuring out how frequently a staffing note needs to be done. One current requirement is for a staffing to occur every 30 days if the patient is seen more than one day per week and every 90 days if seen one day per week or less. This requires providers to count visits, and members report surveyors counting how often the patient is seen and then seeing if staffing notes are meeting the frequency requirement. If retained, it would be more practical to have staffing note frequencies be determined by level of care or license. For example – outpatient could be once every 2 months, Day treatment once per month, etc. This way the service setting would drive the frequency of review and would save providers the time of monitoring how frequently a patient is seen. The value of a staffing note, the intentional review of a patient's care, would still get met but be done so in a way that isn't an administrative burden on the provider.

- The specificity in the current rule regarding progress notes is irrelevant for those services that are using an EHR and all processes specific to paper records should be eliminated.

- Requirements for patient signatures at discharge should be eliminated. It is a cumbersome requirement and impossible when patients don't return for a discharge session despite all effort to encourage them to return. During a previous state survey at least one member was called out for the number of times patients weren't available for signature.

- Requiring a written agreement with outside resources is unnecessary, cumbersome to meet, and should be eliminated in the final rule. Members note that some agencies won't sign "agreements," or add to burden by requiring their legal department's involvement. Additionally, any requirement that the service director approve these agreements is also unnecessary, cumbersome and should be eliminated.

- The current service evaluation section does not add value to patient care and places an additional burden on outpatient clinics.

Next steps

Some stakeholders have suggested that DHS "start over" on DHS 75 rulemaking recognizing the significant amount of work that remains to address the myriad concerns raised by stakeholders. We do agree that before the rule becomes law, additional prioritization should be given to removing barriers to access to care by significantly reducing regulatory burden on and providing additional flexibility to providers providing or considering providing substance use disorder services.

Recognizing the upcoming February 6, 2021 deadline for submission of rule language to the legislature, the significant work to address the concerns raised by WHA, our members, and other stakeholders, and the limited time that WHA members have to carefully engage in further revisions to the proposed rule while managing care during the current COVID pandemic, we look forward to continue working with DHS beyond the February 6, 2021 date to revise proposed DHS 75 before the rule becomes law.

To help make such discussions as meaningful and informed as possible, WHA believes that it is critical that there be a cross walk directly comparing proposed language with current rule language. WHA believes that analysis is critical for all stakeholders, particularly existing entities regulated by DHS 75, to fully understand and meaningfully comment on the practical impact of the proposed rule. As noted earlier, this was a request previously made to DHS.

Thank you again for the invitation to provide comment as part of the Department's proposed repeal and recreation of DHS 75 pursuant to Clearinghouse Rule CR 20-047. We look forward to continuing to work with the Department to achieve the goals of simplifying and streamlining DHS 75 to help remove barriers impacting the accessibility of substance use disorder treatment throughout Wisconsin.

Sincerely,

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