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A Chapter of American Society of Addiction Medicine

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December 13, 2024

Erin Barrett
Director of Legislative and Regulatory Affairs
Department of Health Professions
Virginia Board of Medicine
9960 Mayland Drive, Suite 300
Henrico, VA 23233-1463

Re: Comments and Requested Revisions on Proposal to Amend 18VAC85-21: Regulations Governing Prescribing of Opioids and Buprenorphine

Dear Director Barrett:

On behalf of the Virginia Society of Addiction Medicine (VASAM), thank you for your important work to ensure that the practice of medicine is safe and regulated in our state. Today, we write to comment on the recent proposal to amend **18VAC85-21: Regulations Governing the Prescribing of Opioids and Buprenorphine.**

In brief, to most effectively combat the opioid crisis in Virginia with the latest evidence-based guidelines, we respectfully recommend:

1. Removing psychosocial interventions such as counseling as a requirement for MOUD prescribing

2. Removing additional documentation requirements for buprenorphine doses above 24 mg

3. Removing the restriction on prescribing buprenorphine to patients under 16

While the 18VAC85-21 updated proposal makes tangible improvements compared to the previous iteration, several sections are still out of alignment with clinical best practices in treating opioid use disorder (OUD) and can serve as a barrier to delivering life-saving evidence-based treatment. Specifically, sections restricting MOUD prescribing only to those receiving counseling, restricting the usage of high dosage buprenorphine, and restricting buprenorphine prescribing in adolescents under 16 years conflict with clinical best practice and should be revised.

The regulations for treating OUD with buprenorphine are set forth in Part IV of this section. Specifically, the regulation requires that practitioners engaged in prescribing MOUD also provide either counseling or refer patients to mental health counselors in the

area. While assessing a patient's psychosocial needs is an integral part of the treatment process, we are concerned that this strict requirement may be a barrier to care. Some patients may decline counseling, and some practitioners, especially those in rural or underserved areas, may not have access to readily available mental health counselors.[1] As such, a patient's decision to decline psychosocial treatment or the absence of available psychosocial treatment should not preclude or delay pharmacotherapy, with appropriate medication management. **As such, we urge the Board to revise this section to be in alignment with the Substance Abuse and Mental Health Service Administration's current recommendations that psychosocial interventions such as counseling are strongly encouraged but are not a required condition of treatment.**

Additionally, §18VAC85-21-150 set out further requirements for the treatment of OUD with buprenorphine, including daily dosing. The previous iteration of the regulation set a hard limit on buprenorphine prescriptions of greater than 24 mg per day. This current proposal improves upon that standard and allows for prescriptions of above 24 mg per day with a documented rationale. However, we still believe that requiring documentation for practitioners to prescribe above 24 mg is onerous. For many practitioners, facts on the ground have changed primarily due to the proliferation of high potency synthetic opioids—specifically fentanyl—within the drug supply. In turn, what used to be considered high dosages for stabilization is now standard practice in many cases. For example, the American Society of Addiction Medicine (ASAM) released updated clinical considerations for Buprenorphine Treatment of OUD for Individuals Using High-Potency Synthetic Opioids (HPSOs).[2] Crucially, the clinical considerations reference high quality studies showing improved treatment retention, reduced opioid use, and lack of adverse events at 16-32 mg doses of buprenorphine. These results are echoed by other recent studies of higher dose buprenorphine.[3] **As such, we urge that the dosing guidance be revised to reflect this reality and allow practitioners sufficient flexibility to prescribe at doses above 24 mg per day without additional documentation requirements.**

Finally, §18VAC85-21-160 regulates treatment for special populations with OUD, including adolescents under the age of 16. Specifically, the regulation states that patients under 16 'shall not be prescribed buprenorphine for addiction treatment unless such treatment is approved by the FDA.' This blanket prohibition of providing buprenorphine treatment to patients under 16 is overly restrictive and limits clinicians' authority to provide individualized care, including for adolescents with an imminent risk of overdose. Indeed, ASAM's National Practice Guideline (NPG) [4] stresses the importance of designing specified plans of care to meet each unique circumstance in treating adolescents and encourages clinicians to consider pharmacotherapy, including buprenorphine, as part of 'a full range of treatment options.' Further, ASAM's NPG notes that there are no major safety concerns with pharmacotherapy at a younger age than 16. **As such, VASAM strongly recommends that the Board remove the restriction on prescribing to patients under 16 to allow clinicians the flexibility to treat patients according to their specific needs, including allowing buprenorphine to be prescribed as practicable under federal/state law and sound clinical judgement.**

Thank you for the opportunity to share our comments and concerns regarding the proposed revisions to §18VAC85-21. As stated, we commend the Board for proposing improvements to the previous iteration of this section. However, we still see areas for change.

In summary, to best combat the opioid crisis in Virginia with the latest evidence-based guidelines, we respectfully recommend:

1. Removing counseling as a required component for MOUD prescribing
2. Removing additional documentation requirements for buprenorphine doses above 24 mg
3. Removing the restriction on prescribing buprenorphine to patients under 16

As treatment providers, our primary goal is to ensure that all Virginians can access high-quality treatment for OUD, and we hope to work together with the Board to achieve this goal. Please do not hesitate to contact us if you have any questions or concerns. We appreciate your consideration.

Sincerely,

Debra O'Beirne, MD, FASAM

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President, Virginia Society of Addiction Medicine (VASAM)

CC: Dr. William L. Harp, Virginia Department of Health Professions
Fairfax - Falls Church Community Services Board
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[1] Fenstemaker, C., Abrams, E. A., Obringer, B., King, K., Dhanani, L. Y., & Franz, B. (2024). Primary care professionals' perspectives on tailoring buprenorphine training for rural practice. *The Journal of Rural Health*, *40*(4), 671–680. https://doi.org/10.1111/jrh.12832

[2] Weimer, M. B., Herring, A. A., Kawasaki, S. S., Meyer, M., Kleykamp, B. A., & Ramsey, K. S. (2023). ASAM Clinical Considerations: Buprenorphine Treatment of Opioid Use Disorder for Individuals Using High-potency Synthetic Opioids. Journal of Addiction Medicine, 17(6), 632–639. https://doi.org/10.1097/adm.0000000000001202

[3] Chambers, L. C., Hallowell, B. D., Zullo, A. R., Paiva, T. J., Berk, J., Gaither, R., Hampson, A. J., Beaudoin, F. L., & Wightman, R. S. (2023). Buprenorphine Dose and Time to Discontinuation Among Patients With Opioid Use Disorder in the Era of Fentanyl. JAMA Network Open, 6(9). https://doi.org/10.1001/jamanetworkopen.2023.34540

[4] American Society of Addiction Medicine - ASAM. (2020). The ASAM National Practice Guideline For the Treatment of Opioid Use Disorder: 2020 Focused Update. Journal of Addiction Medicine, 14(2S), 1–91. https://doi.org/10.1097/adm.0000000000000633