Friday, February 10, 2017

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William L. Harp, MD
Executive Director
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Dear Drs. Allison-Bryan and Harp,

On behalf of the American Society of Addiction Medicine (ASAM), a national medical specialty organization representing more than 4,300 physicians and other clinicians who specialize in the treatment of addiction, and the Virginia Society of Addiction Medicine (VASAM), we would like to take the opportunity to provide comments on the proposed regulations, Governing Opioid Prescribing for Pain and Prescribing of Buprenorphine for Office-Based Opioid Addiction Treatment. With the opioid addiction and overdose epidemic still significantly impacting the country and Virginia, VASAM and ASAM appreciate the effort to ensure patients in Virginia are receiving high-quality and comprehensive addiction treatment.

VASAM and ASAM are wholeheartedly committed to preventing the diversion of medications that are used to treat opioid addiction. At the same time, it is vitally important that regulations targeting diversion do not inadvertently limit access to treatment. With the passage of HB2163 and SB1178 likely in the Virginia legislature, which require products containing buprenorphine without naloxone to be issued only for a patient who is pregnant and give the Virginia Board of Medicine the authority to make exceptions to the limits on buprenorphine mono-product, it is vitally important that the regulations establishing the guidelines for the prescribing of buprenorphine mono-product do not restrict access to current or future medications for the treatment of opioid addiction that could significantly improve a patient's care.

General Comments

Part IV of these regulations addresses the prescribing of buprenorphine for office-based opioid treatment (OBOT) and we believe there are certain provisions within it that should be revised to reflect the advancements in knowledge and innovation of the addiction medicine field. Under 18VAC85-21-150, regarding treatment with buprenorphine, provision A restricts buprenorphine mono-product

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formulations to only be prescribed to pregnant patients or those transitioning from methadone to buprenorphine for addiction treatment. It is expected that two new formulations of injectable buprenorphine mono-product will be approved in early 2018. VASAM and ASAM recommend clarifying in provision A that it is just the oral formulations of buprenorphine mono-product that can only be prescribed to pregnant patients or those converting from methadone to buprenorphine containing naloxone. This clarification will ensure that those restrictions do not apply to the formulations listed in provision D. We also request that the Virginia Board of Medicine revisit these regulations to consider updates to provision D when new formulations of buprenorphine mono-product are approved.

Special populations are addressed under 18VAC85-21-160 and we propose an update to the language of provision E regarding the treatment of patients with co-occurring psychiatric disorders. Co-occurring psychiatric disorders should not bar patients from opioid addiction treatment or addiction treatment in general. Part 11 of ASAM's National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use provides clinical recommendations on treating individuals with co-occurring psychiatric disorders. It highlights that the assessment of psychiatric disorders is critical when attempting to place patients in the appropriate treatment. An initial patient assessment should determine whether the patient is stable and hospitalization may be appropriate for patients with severe or unstable psychiatric symptoms that may compromise the safety of self and others. Patients should also be assessed for signs or symptoms of acute psychosis and chronic psychiatric disorders. While actively suicidal patients are not good candidates to begin any opioid treatment, pharmacological and conjunctive psychosocial treatments should be considered for patients with both an opioid addiction and a psychiatric disorder. The first sentence of this provision should be updated to state, "practitioners shall not undertake buprenorphine treatment with a patient who has psychiatric comorbidities and is not stable unless the comorbidities result or are exacerbated from substance misuse and are likely to stabilize with buprenorphine treatment."

Specific Comments

VASAM and ASAM recommend substituting the term "substance abuse" with "substance misuse" throughout the entire regulations. The stigma surrounding the disease of addiction continues to be a barrier to individuals with addiction seeking the help they need. By including non-stigmatizing words in our legislation and regulation, legislatures and agencies can help reduce that stigma.

Under 18VAC85-21-10, regarding the applicability of the regulations, provision A does not include nurse practitioners. Since nurse practitioners treat both patients with pain and addiction, and are now allowed by federal law to be waived to prescribe buprenorphine, we recommend that they be included in the scope of these regulations.

The definition for chronic pain listed under 18VAC85-21-20 distinguishes between chronic non-malignant pain and chronic malignant pain. We believe this may be unnecessary, as there are many patients who have resolved malignancies and they should be treated the same as chronic non-malignant pain patients.

Treatment of acute pain with opioids is addressed under 18VAC85-21-40. We recommend that provision D is updated to state, "buprenorphine is not indicated for acute pain in the outpatient setting, except when a waivered buprenorphine prescriber is treating pain in a patient whose primary diagnosis is the disease of addiction." VASAM and ASAM find this important because we

educate new buprenorphine prescribers on how to deal with pain in their patients from certain events, such as surgeries and dental procedures, and that education includes prescribing buprenorphine in small doses for short periods to deal with that acute pain.

VASAM and ASAM recommend changing the end of provision B under 18VAC85-21-90, so that it reads, "there shall be a written treatment agreement in the medical record that addresses the parameters of treatment, including those behaviors which will result in a cessation of treatment or referral to a higher level of care."

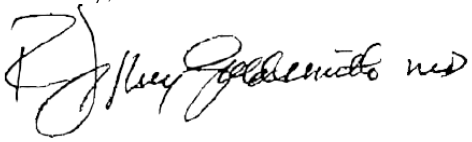
Under 18VAC85-21-100, the language of provision D should be updated to state, "practitioner shall order and review a urine drug screen or serum medication levels at the initiation of chronic pain management and every three months thereafter."

Provision A of 18VAC85-21-140, regarding patient assessment and treatment planning, does not take into account that withholding appropriate buprenorphine treatment for a woman of childbearing age while waiting for a pregnancy test may lead to relapse, death or withdrawal, which is detrimental to the fetus. VASAM and ASAM recommend that situation be factored into this provision.

Conclusion

VASAM and ASAM share the state of Virginia's goal of supporting access to high quality and comprehensive addiction treatment and reducing the diversion of opioids, as well as improving the practices of prescribing opioids for acute and chronic pain. We are committed to working with the Virginia Board of Medicine as they implement these regulations. We anticipate HB2163 and SB1178 to provide more authority to the Board over these regulations and ask that you take into consideration the implantable and injectable buprenorphine mono-product formulations to be allowed for all patients, as well as our concerns around dosage and populations with co-occurring psychiatric disorders. Aside from these provisions, the proposed regulations are quite reasonable and commendable. Provided the adjustments of those provisions takes place, these regulations may be good models for other states to emulate to effectively address the opioid addiction and overdose epidemic. Please do not hesitate to contact Brad Bachman, Manager of State Government Relations, at (301) 547-4107 or bbachman@asam.org if VASAM and ASAM can be of service to you. We thank you for this opportunity to provide comments on the proposed regulations for OBOT with buprenorphine.

Sincerely,



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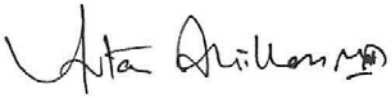

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