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Addiction Medicine

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Thursday, February 2, 2017

The Honorable Mary Taylor  
Lt. Governor of Ohio  
Common Sense Initiative  
Riffe Center, 30<sup>th</sup> Floor  
77 South High St  
Columbus, OH 43215-6117

Steven Schierholt, ESQ.  
Executive Director  
State of Ohio Board of Pharmacy  
Riffe Center, 17<sup>th</sup> Floor  
77 South High St  
Columbus, OH 43215-6117

Dear Lt. Governor Taylor and Mr. Schierholt,

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 Ohio Society of Addiction Medicine (OHSAM), we thank you for the opportunity to comment on the proposed rules for implementing SB319. With the opioid addiction and overdose epidemic still significantly impacting the country and, in particular, Ohio, OHSAM and ASAM appreciate the effort to ensure patients in Ohio are receiving high-quality and comprehensive addiction treatment.

OHSAM 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. As SB319 is implemented through the state's rule making process, OHSAM and ASAM ask that the State of Ohio Board of Pharmacy and the Department of Mental Health and Addiction Services provide education and clarity to providers of office-based opioid treatment (OBOT) of what is now required and expected from them.

As the proposed rules are being implemented, OHSAM and ASAM ask for the State of Ohio Board of Pharmacy to make it clear that

the intention of these rules is to cover only OBOT providers that prescribe medicines or OBOT providers that distribute medicines. We also recommend that the State of Ohio Board of Pharmacy specifically outline which issues may be reviewed on a case-by-case basis when obtaining a category III terminal distributor of dangerous drugs license, such as those raised in this letter.

The new rules being proposed to regulate OBOT providers require owners and responsible persons at an OBOT location to obtain a category III license. It is imperative that the OBOT providers who will now be required to obtain this license are informed of this new requirement and connected with the appropriate resources to apply for that license. In addition, there must be transparency of how the category III license will be approved within a certain timeline and if those OBOT providers can continue to treat their patients with opioid addiction while they are waiting for that approval. If their patients cannot be treated while the provider is awaiting licensure, those patients must be connected with other treatment providers.

The rules' requirements for the operations of OBOT are narrow in suggesting that the category III license holder must be in control of a facility that is owned and operated solely by one or more physicians authorized by the State Medical Board to practice allopathic or osteopathic medicine. This does not consider that OBOT providers may open a practice with a behavioral health provider to offer comprehensive care and that the behavioral health provider may want to be the owner and operator of the facility. The State of Ohio Board of Pharmacy has informed OHSAM and ASAM that they will consider the ownership requirement on a case-by-case basis. This information should be disseminated to OBOT providers as they prepare to obtain licensure.

Under these proposed rules, the State of Ohio Board of Pharmacy has authority to suspend the licenses of OBOT providers who fail to obtain the required licensure or comply with SB319's requirements without a hearing beforehand. OHSAM and ASAM have been assured by the State of Ohio Board of Pharmacy that those providers will still be entitled to a hearing to appeal that suspension. We recommend this be made clear when OBOT providers obtain their new category III license and when they receive their initial notice of licensure suspension. In addition, the State of Ohio Board of Pharmacy has different investigation standards and procedures for providers that hold different medical licenses. The OBOT providers who obtain a category III license should be made aware of how those investigations are carried out to ensure they are in compliance with the rules. If OHSAM and ASAM can assist in providing quality standards to assist Ohio physicians to comply, we would be happy to do so.

The proposed rules would prevent physicians with previous licensure infractions from owning an OBOT location. This may seem to fit alongside the requirement for physician owners or officers of an OBOT to submit to a criminal record check with the Bureau of Criminal Identification & Investigation (BCI&I) and Federal Bureau of Investigation (FBI) before issuance of a license. Yet it may have the unintended consequence of barring physicians who are in long-term recovery from owning their own practice. There are many

physicians, both generally and in the addiction medicine field, who are in long-term recovery. It can take many physicians up to five years to reenter the workforce after undergoing addiction treatment and, for those in the field of addiction medicine, this could be an incentive not to come back to practice. The State of Ohio Board of Pharmacy has told OHSAM and ASAM that they would allow exceptions based on strong cases made on behalf of the physician. This information should be disseminated to OBOT providers as they prepare to obtain licensure.

OHSAM and ASAM share the state of Ohio's goal in eliminating the diversion of medications that are used to treat opioid addiction and are committed to working with the State of Ohio Board of Pharmacy as they implement SB319. Please do not hesitate to contact Brad Bachman, Manager of State Government Relations, at (301) 547-4107 or [bbachman@asam.org](mailto:bbachman@asam.org), if OHSAM or ASAM can be of service to you. We thank you for this opportunity to comment on the proposed rules for implementing SB319.

Sincerely,

A handwritten signature in black ink, appearing to read "R. Jeffrey Goldsmith". The signature is fluid and cursive, with a prominent initial "R".

R. Jeffrey Goldsmith, MD, DLFAPA, DFASAM  
President, American Society of Addiction Medicine

A handwritten signature in black ink, appearing to read "Shawn Ryan". The signature is fluid and cursive, with a prominent initial "S".

Shawn Ryan, MD, MBA, FASAM  
President, Ohio Society of Addiction Medicine