



SB 229 Proponent Testimony

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Chair Burke, Vice-Chair Beagle, Ranking Member Tavares and members of the Senate Health, Human Services and Medicaid Committee, thank you for the opportunity to provide proponent testimony on the Senate Bill 229. My name is Steve Schierholt and I am the Executive Director of the State Board of Pharmacy. SB 229 contains several important policy proposals to assist the Board of Pharmacy in regulating the distribution of controlled substances to protect the health and safety of Ohioans.

The primary focus of this legislation is an update to Ohio's Controlled Substances Act, Chapter 3719. of the Ohio Revised Code. Per section 3719.28 of the Revised Code, the Board of Pharmacy is charged with the enforcement of this chapter. As such, the Board currently has the authority to designate drugs or compounds as controlled substances if they meet certain requirements outlined in the Revised Code.

The Board has used this authority several times in the past to schedule specific compounds as Schedule I controlled substances on an emergency basis. For example, in May 2016, the Board outlawed a synthetic opioid that was being imported from China, known as U-47700, that is seven and a half times more potent than morphine after reports that the drug had contributed to several overdoses in Northeast Ohio.

While a process exists to outlaw potentially deadly compounds on an emergency basis, SB 229 seeks to allow the Board to quickly address the growing issue of the importation of novel substances manufactured overseas by making the following modifications to expedite this process:

- 1. Reducing the number of criteria required to be considered to make a compound a Schedule I controlled substance on an emergency basis.** This matches the same criteria used by the DEA and would include all the following: 1) The history and current pattern of abuse; 2) The scope, duration and significance of abuse; and 3) The risk to public health.

Please be advised that the legislation would not allow the Board to schedule anything that has been approved for use by the FDA and still requires an emergency order to be issued by the Governor.

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2. Permitting the Board to meet via conference call to make the determination that the substance meets the emergency scheduling requirements. As Board members are busy professionals practicing throughout Ohio, it may be difficult to obtain a in-person quorum to address an emergency. Therefore, the bill will allow the Board to meet via conference call, as it is already authorized to do to summarily suspend a license in the event of an immediate and serious threat to the public.

Additionally, the bill moves all currently listed controlled substances from the Revised Code to the Administrative Code. This allows Ohio to maintain one specific location where law enforcement and prosecutors can determine how Ohio classifies a compound or drug. By adopting this proposal, Ohio would join 25 other states currently listing controlled substances in administrative rule.

Moving to administrative rule also addresses a current issue where a number of drugs listed in section 3719.41 of the Revised Code do not conform to federal law. For example, there are several new controlled substances that are not currently listed and some that are incorrectly classified. Hydrocodone, an opioid subject to abuse, is currently listed in state law as a Schedule III controlled substance when, federally, it is a Schedule II controlled substance. To ensure Ohio remains consistent and up-to-date with federal changes, the legislation creates an expedited process for the Board to update rules to match the federal schedule.

In addition to modifications to controlled substance schedules, the legislation also makes the following changes:

1) Protection of Employee Information

As an agency charged with enforcing criminal drug laws, Board staff often receive threats and have been subject to acts of violence from individuals who are subject to investigation/prosecution. To protect our investigators and staff, the Board proposes to shield their personal information and the information of their families from public records laws.

2) Legislative Correction to ORC 3719.09

A court case from the 9th District in 2009 identified an issue regarding the definition of what constitutes a lawful prescription in section 3719.09 of the Revised Code. This issue was previously identified and subsequently addressed in Chapter 2925. by the 127th General Assembly. The legislation seeks to make the same legislative fix provided by the 127th General Assembly in section 3719.09 to be able to pursue prosecutions for illegal possession of dangerous drugs.

3) Correction to the 14-day Limit on Opioid Prescriptions

The bill seeks to clarify an issue with a provision of SB 319 (131st General Assembly) whereby the language voids all prescriptions for opioid analgesics after 14-days from the date they were written.

Current law does not specifically address refills of opioid prescriptions but it has been interpreted by some that this provision applies, which has resulted in some confusion amongst the pharmacy community. SB 229 would ensure that the 14-day limit only applies to an initial fill of an opioid prescription.

The bill also clarifies that the remaining portions of partially dispensed opioid prescriptions are not subject to the 14-day limit. This is practice that is intended to reduce opioid prescriptions by only filling a portion of the prescription as requested by the patient or prescriber. If pharmacists or prescribers interpret this section to preclude this practice, it removes a valuable tool intended to reduce the number of opioid pills dispensed.

4) Office-Based Opioid Treatment Facilities

Lastly, the bill makes some modifications governing the licensure of office-based opioid treatment facilities by the Board of Pharmacy. These are facilities where a prescriber is treating more than 30 patients for opioid use disorder using controlled substances such as buprenorphine, commonly known as Suboxone®.

After the completion of the initial licensing process and feedback from the prescriber community, the Board is proposing the following changes:

- Exemption of Federally Qualified Health Centers (FQHCs) from licensure requirements. FQHCs provide services in underserved areas and are operated by non-profits with governing boards. They are typically already licensed by the Board as terminal distributors because they often possess drugs on-site. They are certified by the federal government and must provide comprehensive health services. Therefore, the Board feels that they should be exempted from licensure.
- Exemption of correctional facilities from licensure. To remove any potential barriers to the provision of treatment in jails, the Board proposes to exempt jails and prisons from license as an office-based opioid treatment facility. Like FQHCs, these facilities already possess a standard terminal distributor license by the Board of Pharmacy as they have drugs on-site.
- The Board also proposes a look-back period of ten years for the automatic exclusion of employment for a felony drug or theft offense. It has come to the Board's attention that individuals who may have had drug issues in the past may be more inclined to assist those dealing with addiction issues and therefore a blanket prohibition may not be appropriate.

I would like to note that this proposal has been included as an amendment adopted by this committee to HB 101.

On behalf of the Board of Pharmacy, I would like to thank Senator Eklund and Senator Lehner for their sponsorship of Senate Bill 229. This legislation includes important reforms that will strengthen Ohio's efforts to address illicit drugs and implement needed reforms to assist the

Board in its mission to promote and protect the health and safety of all Ohioans. I would be happy to answer any questions you may have at this time.