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## H.B. 601\*

132nd General Assembly (As Reported by H. Health)

Ginter Rep.

### **BILL SUMMARY**

- Authorizes a pharmacist to administer by injection any drug used for treatment of drug addiction that is prescribed by a physician and administered in a long-acting or extended-release form, rather than limiting the authority to administering opioid antagonists.
- Exempts from office-based opioid treatment licensure by the State Board of Pharmacy a place in which patients are treated for opioid dependence or addiction through direct administration of addiction treatment drugs by a physician, advanced practice registered nurse, or physician assistant.
- Provides that patients treated for opioid dependence or addiction through direct administration of drugs are not counted for purposes of determining whether an office-based opioid treatment provider must be licensed by the Board.

### CONTENT AND OPERATION

# Pharmacist injection of addiction treatment drugs

The bill authorizes a pharmacist to administer by injection any drug prescribed by a physician that is used for treatment of drug addiction and administered in a longacting or extended-release form.1 Current law permits a pharmacist to inject certain drugs. These drugs include a long-acting or extended-release opioid antagonist used to

<sup>\*</sup> This analysis was prepared before the report of the House Health Committee appeared in the House Journal. Note that the list of co-sponsors and the legislative history may be incomplete.

<sup>&</sup>lt;sup>1</sup> R.C. 4729.45(B)(1)(a).

treat drug addiction. The bill extends this authorization to all long-acting or extended-release addiction treatment drugs.

An **opioid antagonist** is a drug, such as naltrexone, that blocks the action of opioids. Other drugs used for addiction treatment include **agonists** such as methadone, which are slow-acting opioids, and **partial agonists** like buprenorphine, which combine an agonist with an antagonist.<sup>2</sup> It appears that the only addiction treatment drug other than naltrexone that is currently available for administration by injection is Sublocade, a once-monthly buprenorphine injection, which was approved by the United States Food and Drug Administration in 2017.<sup>3</sup>

Under current law maintained by the bill, a pharmacist is authorized to administer a drug by injection if the drug is prescribed by a physician and there is an ongoing physician-patient relationship. The bill maintains other requirements of current law applicable to injections by a pharmacist, including the requirement that the pharmacist follow a protocol established by a physician<sup>4</sup> and requirements concerning pharmacist education, patient permission, patient observation, physician notice, and, in the case of injections for addiction treatment, blood or urine testing to determine whether it is appropriate to administer the drug.<sup>5</sup>

## Office-based opioid treatment

Under current law "office-based opioid treatment" is the treatment of opioid dependence or addiction using a controlled substance.<sup>6</sup> Subject to several exemptions, current law generally requires a facility, clinic, or location where a prescriber provides office-based opioid treatment to more than 30 patients to hold a category III terminal distributor of dangerous drugs license with an office-based opioid treatment classification issued by the State Board of Pharmacy.<sup>7</sup>

<sup>&</sup>lt;sup>7</sup> R.C. 4729.553(B)(1).



<sup>&</sup>lt;sup>2</sup> Heroin, United States Department of Health and Human Services, National Institutes of Health, Publication 15-0165, published October 1997, last revised November 2014, available at <a href="https://d14rmgtrwzf5a.cloudfront.net/sites/default/files/heroinrrs\_11\_14.pdf">https://d14rmgtrwzf5a.cloudfront.net/sites/default/files/heroinrrs\_11\_14.pdf</a>

<sup>&</sup>lt;sup>3</sup> FDA approves first once-monthly buprenorphine injection, a medication-assisted treatment option for opioid use disorder, United States Food and Drug Administration, November 30, 2017, available at <a href="https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm587312.htm">https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm587312.htm</a>.

<sup>&</sup>lt;sup>4</sup> R.C. 4729.45(C).

<sup>&</sup>lt;sup>5</sup> R.C. 4729.45(C), (D), (E), and (F).

<sup>&</sup>lt;sup>6</sup> R.C. 4729.553(A)(4).

The bill exempts from the licensure requirement a place in which patients are treated for opioid dependence or addiction through direct administration of addiction treatment drugs by a physician, physician assistant, or advanced practice registered nurse and the drugs are not dispensed to patients for self-administration.<sup>8</sup> The bill also specifies that patients who receive treatment for opioid dependence or addiction by this direct administration of drugs are not to be included when determining whether more than 30 patients are being provided office-based opioid treatment at a particular location.<sup>9</sup>

Facilities currently exempted from office-based opioid treatment licensure include (1) hospitals and hospital-operated facilities and practices, (2) clinical research facilities, (3) federally regulated opioid treatment programs, and (4) programs and facilities licensed or certified by the Department of Mental Health and Addiction Services.<sup>10</sup> These exemptions are maintained by the bill.

#### **HISTORY**

ACTION DATE

Introduced 04-17-18 Reported, H. Health ---

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<sup>&</sup>lt;sup>10</sup> R.C. 4729.553(B)(2).



<sup>&</sup>lt;sup>8</sup> R.C. 4729.553(B)(2)(a)(vii).

<sup>&</sup>lt;sup>9</sup> R.C. 4729.553(B)(2)(b).