



# Ohio Legislative Service Commission

## Bill Analysis

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### Sub. H.B. 378

130th General Assembly  
(As Reported by H. Health and Aging)

**Reps.** Smith and Sprague, Wachtmann, Brown, Sears

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## BILL SUMMARY

- Requires the State Medical Board to establish, by rule, standards and procedures for physicians to follow in using controlled substances to treat opioid dependence or addiction.
- Establishes criminal penalties, which are in addition to existing administrative fines, for prescribers who violate the limits on the amount of controlled substances that may be personally furnished to patients.
- Modifies the conditions under which buprenorphine is not included in determining whether prescribers have exceeded their limits on personally furnishing controlled substances.
- Requires, beginning April 1, 2015, that certain prescriber-based business entities hold a terminal distributor license from the State Board of Pharmacy in order to possess and distribute buprenorphine-containing drugs used to treat drug dependence or addiction.

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## CONTENT AND OPERATION

### Physician use of controlled substances to treat dependence or addiction

The bill requires the State Medical Board to establish standards and procedures to be followed by physicians when using schedule III, IV, or V controlled substances to treat opioid dependence or addiction. The bill authorizes the Board to specify the practice type or location in which the standards and procedures are to apply.<sup>1</sup>

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<sup>1</sup> R.C. 4731.056.

The standards and procedures are to be established in rules adopted by the Board in accordance with the Administrative Procedure Act (R.C. Chapter 119.). The standards and procedures are applicable to physicians who are medical doctors or osteopathic doctors.

## **Limits on personally furnishing controlled substances**

### **Criminal penalties**

The bill establishes criminal penalties for violating existing limits on the amount of controlled substances a prescriber may personally furnish to or for patients. Under these limits, which are unchanged by the bill, a prescriber (other than a veterinarian) cannot personally furnish more than either of the following:

- 2,500 dosage units in a 30-day period to all patients taken as a whole;
- A 72-hour supply for a patient's use in that period.<sup>2</sup>

The bill provides that a prescriber who violates these limits is guilty of a first degree misdemeanor for a first offense and a fifth degree felony for a subsequent offense.<sup>3</sup> The bill's criminal penalties are in addition to the fines of not more than \$5,000 that the State Board of Pharmacy is authorized to impose under current law.<sup>4</sup>

### **Exception for buprenorphine**

The bill modifies the conditions under which buprenorphine is not included in determining whether a prescriber has exceeded the limits on personally furnishing controlled substances to patients.<sup>5</sup> Buprenorphine, which is used to treat opioid dependence, prevents withdrawal symptoms when someone stops taking opioid drugs by producing similar effects to the opioid drugs.<sup>6</sup>

Under current law, buprenorphine is excluded from consideration in determining whether the limits have been exceeded if the buprenorphine is provided to treat drug addiction by a prescriber who satisfies federal requirements so as to be

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<sup>2</sup> R.C. 4729.291(C)(1).

<sup>3</sup> R.C. 4729.99(L).

<sup>4</sup> R.C. 4729.291(C)(2).

<sup>5</sup> R.C. 4729.291(D).

<sup>6</sup> U.S. National Library of Medicine, National Institutes of Health, *Buprenorphine Sublingual* (last visited December 2, 2014), available at < <http://www.nlm.nih.gov/medlineplus/druginfo/meds/a605002.html>>.



exempt from separate registration with the federal Drug Enforcement Administration.<sup>7</sup> The bill replaces this provision with a provision that excludes buprenorphine that is provided to treat drug addiction as part of an opioid treatment program. For the exclusion to apply, the opioid treatment program must (1) be certified by the federal Substance Abuse and Mental Health Services Administration and (2) must distribute both buprenorphine and methadone.

### **Terminal distributor license for prescriber businesses using buprenorphine**

Under current law, certain prescriber-based business entities that possess dangerous drugs are exempt from the general requirement to be licensed by the State Board of Pharmacy as terminal distributors of dangerous drugs. For the exemption to apply, each shareholder, member, or partner of the business entity must be authorized to prescribe drugs and authorized to provide the health care professional services offered by the entity.<sup>8</sup>

Beginning April 1, 2015, the bill requires such a business entity to hold a terminal distributor license in circumstances involving buprenorphine. Specifically, the business entity must be licensed in order to possess, have custody or control of, and distribute controlled substances containing buprenorphine that are used for the purpose of treating drug dependence or addiction.<sup>9</sup>

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## **HISTORY**

<b>ACTION</b>	<b>DATE</b>
Introduced	12-05-13
Reported, H. Health & Aging	11-19-14

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<sup>7</sup> R.C. 4729.291(D)(1)(b); *see also* 21 Code of Federal Regulations 1301.28.

<sup>8</sup> R.C. 4729.51, not in the bill and 4729.541.

<sup>9</sup> R.C. 4729.541(C)(2).

