



# Ohio Legislative Service Commission

## Bill Analysis

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### H.B. 378

130th General Assembly  
(As Introduced)

Reps. Smith and Sprague

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## BILL SUMMARY

- Prohibits a physician from prescribing or personally furnishing certain medications to treat dependence on or addiction to opioids unless the physician has been certified by the medical director of the department of Mental Health and Addiction Services.
- Prohibits a physician from prescribing or personally furnishing the medications to a patient who is not actively participating in appropriate behavioral counseling or treatment.

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## CONTENT AND OPERATION

### Opioid treatment with medication

The bill establishes procedures a physician, including a podiatrist,<sup>1</sup> must follow when using a drug containing buprenorphine, methadone, or naltrexone to treat a patient who is dependent on or addicted to opioids.

#### Physician certification

The bill prohibits a physician from prescribing or personally furnishing buprenorphine, methadone, or naltrexone, for the purpose of treating a patient's dependence on or addiction to opioids, without receiving certification from the medical director of the Department of Mental Health and Addiction Services.<sup>2</sup> The bill requires the Director of Mental Health and Addiction Services to establish a program for the

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<sup>1</sup> R.C. 4731.056(A).

<sup>2</sup> R.C. 4731.056(B)(3).

certification of physicians as qualified by training and experience to prescribe or personally furnish the drugs in conjunction with behavioral counseling or treatment. The bill adds physician certification to the medical director's statutory responsibilities.<sup>3</sup>

A physician who prescribes or personally furnishes these drugs without certification will be subject to professional disciplinary action by the State Medical Board.<sup>4</sup>

### **Patient participation in counseling or treatment**

A physician who has secured the certificate may not prescribe or personally furnish the medications described above to a patient unless that patient provides evidence demonstrating active participation in appropriate behavioral counseling or treatment.<sup>5</sup> The treating physician must document the evidence in the patient's medical record.<sup>6</sup>

## **Medications for opioid use**

### **Buprenorphine**

According to the U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration (SAMHSA), buprenorphine is an opioid partial agonist. Although it is an opioid and can produce typical opioid agonist effects and side effects such as euphoria and respiratory depression, its maximal effects are less than those of full agonists like heroin and methadone. Buprenorphine carries a lower risk of abuse, addiction, and side effects compared to full opioid agonists. In high doses and under certain circumstances, buprenorphine can actually block the effects of full opioid agonists and can precipitate withdrawal symptoms if administered to an opioid-addicted individual while a full agonist is in the bloodstream.<sup>7</sup>

### **Methadone**

The Office of National Drug Control Policy explains that methadone is a synthetic opioid that mitigates opioid withdrawal symptoms and, at higher doses, blocks

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<sup>3</sup> R.C. 4731.056(C) and 5119.11(A)(4).

<sup>4</sup> R.C. 4731.22(B)(20) (not in the bill).

<sup>5</sup> R.C. 4731.056(B)(1).

<sup>6</sup> R.C. 4731.056(B)(2).

<sup>7</sup> *About Buprenorphine Therapy* (last visited December 13, 2013), available at <<http://buprenorphine.samhsa.gov/about.html>>.



the effects of heroin and other drugs containing opioids.<sup>8</sup> Under federal law, methadone can be dispensed to treat a dependence on or addition to opioids only at an outpatient treatment program certified by SAMHSA and registered with the U.S. Department of Justice, Drug Enforcement Administration (DEA) or to a hospitalized patient in an emergency.

## **Naltrexone**

Naltrexone is a non-opioid medication for the treatment of opioid dependence.<sup>9</sup> Unlike methadone and buprenorphine, this medication is *not* a controlled substance and is subject to significantly less regulation. Naltrexone is an opioid receptor antagonist; it binds to opioid receptors, but instead of activating the receptors, it effectively blocks them. Through this action, it prevents opioid receptors from being activated by agonist compounds, such as heroin or prescription pain killers, and is reported to reduce craving and prevent relapse. If a patient who has been administered naltrexone attempts to continue taking opioids, he or she is unable to feel any of the opioid's effects due to naltrexone's blocking action.<sup>10</sup>

## **Federal law**

### **Clinics that provide methadone**

Under federal law, physicians who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment must obtain an annual registration with the federal Attorney General.<sup>11</sup> The clinics where treatment is provided must be certified by SAMHSA.<sup>12</sup> (In Ohio, a community addiction services provider that employs methadone also must be licensed by the Department of Mental Health and Addiction Services.<sup>13</sup> With a few exceptions, these clinics are restricted to treating patients who have been addicted to opioids for a least one year.<sup>14</sup>

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<sup>8</sup> Office of National Drug Control Policy. *Medication-Assisted Treatment for Opioid Addiction* (last visited December 13, 2013), available at <[www.whitehouse.gov/sites/default/files/ondcp/recovery/medication\\_assisted\\_treatment\\_9-21-20121.pdf](http://www.whitehouse.gov/sites/default/files/ondcp/recovery/medication_assisted_treatment_9-21-20121.pdf)>

<sup>9</sup> *Naltrexone* (last visited December 13, 2013), available at <<http://www.dpt.samhsa.gov/medications/naltrexone.aspx>>.

<sup>10</sup> *Medication-Assisted Treatment for Opioid Addiction* at 3.

<sup>11</sup> 21 United States Code (U.S.C.) 823(g)(1).

<sup>12</sup> 42 Code of Federal Regulations (C.F.R.) 8.11(a).

<sup>13</sup> R.C. 5119.39.

<sup>14</sup> 42 C.F.R. 8.12(e).



Among other federal requirements, each clinic must provide adequate medical, counseling, vocational, educational, and other assessment and treatment services.<sup>15</sup> Moreover, each clinic must provide adequate substance abuse counseling to each patient as clinically necessary. The counseling must be provided by a program counselor, qualified by education, training, or experience to assess the psychological and sociological background of patients, to contribute to the appropriate treatment plan for the patient and to monitor patient progress.<sup>16</sup>

### **Office-based treatment with drugs that contain buprenorphine**

Under the federal Drug Addiction Treatment Act of 2000, waivers from the Controlled Substances Act may be granted by the Drug Enforcement Administration to physicians who meet certain qualifications to treat opioid addiction with schedule III, IV, and V narcotic medications.<sup>17</sup> Such medications may be prescribed and dispensed by these physicians in treatment settings other than the traditional methadone clinic setting.<sup>18</sup> To qualify for a waiver, a physician must meet one or more of the following criteria:<sup>19</sup>

- Hold a subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties;
- Hold an addiction certification from the American Society of Addiction Medicine;
- Hold a subspecialty board certification in addiction medicine from the American Osteopathic Association;
- Have, with respect to the treatment and management of opioid-addicted patients, completed not less than eight hours of training provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or another organization the Secretary of Health and Human Services determines is appropriate;

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<sup>15</sup> 42 C.F.R. 8.12(f)(1).

<sup>16</sup> 42 C.F.R. 8.12(f)(5).

<sup>17</sup> 114 Stat. 1101; 106 Public Law 310, Children's Health Act of 2000.

<sup>18</sup> Substance Abuse and Mental Health Services Administration (last visited December 16, 2013), available at <<http://buprenorphine.samhsa.gov/data.html>>.

<sup>19</sup> 21 U.S.C. 823(g)(2)(G)(ii).



- Have participated as an investigator in one or more clinical trials leading to the approval of a narcotic drug in schedule III, IV, or V for maintenance or detoxification treatment, as demonstrated by a statement submitted to the Secretary by the drug's sponsor;
- Have such other training or experience as the medical licensing board of the state in which the physician will provide maintenance or detoxification treatment considers to demonstrate the ability of the physician to treat and manage opioid-addicted patients;
- Have such other training or experience as the Secretary considers to demonstrate the ability of the physician to treat and manage opioid-addicted patients.

Additionally, the physician must have the capacity to refer the patients for appropriate counseling and other appropriate ancillary services.<sup>20</sup> Once the waiver is approved, the physician may treat up to 30 patients at one time with buprenorphine. After one year, the physician may apply to the DEA to treat up to 100 patients.<sup>21</sup>

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## HISTORY

ACTION	DATE
Introduced	12-05-13

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<sup>20</sup> 21 U.S.C. 823(g)(2)(B)(ii).

<sup>21</sup> 21 U.S.C. 823(g)(2)(B)(iii).

