



Guidance Document: Changes in Ohio Law Impacting Buprenorphine Used for the Purpose of Treating Drug Dependence or Addiction

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Ohio [HB 367 \(130th General Assembly\)](#) was recently signed into law. Prescribers need to be aware that the law includes the following two provisions relating to controlled substances containing buprenorphine used for the purpose of treating drug dependence or addiction:

- 1) Effective July 16, 2015, ORC 4729.291 states a prescriber may not do either of the following:
 - (I) In any thirty-day period, personally furnish to or for patients, taken as a whole, controlled substances containing buprenorphine in an amount that exceeds a total of two thousand five hundred dosage units; or
 - (II) In any seventy-two-hour period, personally furnish to or for a patient an amount of a controlled substance containing buprenorphine that exceeds the amount necessary for the patient's use in a seventy-two-hour period.

PLEASE NOTE: THIS ONLY APPLIES TO BUPRENORPHINE THAT IS PERSONALLY FURNISHED (i.e. physician dispensed in an out-patient setting). THESE RESTRICTIONS DO NOT APPLY TO BUPRENORPHINE PRODUCTS THAT ARE ADMINISTERED IN AN IN-PATIENT SETTING OR PRESCRIPTIONS FOR BUPRENORPHINE PRODUCTS THAT ARE FILLED BY A PHARMACY IN ACCORDANCE WITH STATE AND FEDERAL LAW.

2) Effective April 1, 2015, ORC 4729.541 will require the following business entities to hold a license as a terminal distributor of dangerous drugs in order to possess, have custody or control of, and dispense **controlled substances containing buprenorphine that are used for the purpose of treating drug dependence or addiction:**

- (I) A business entity that is a corporation formed under division (B) of section 1701.03 of the Revised Code, a limited liability company formed under Chapter 1705. of the Revised Code, or a professional association formed under Chapter 1785. of the Revised Code if the entity has a sole shareholder who is a licensed health professional authorized to prescribe drugs and is authorized to provide the professional services being offered by the entity; or
- (II) A limited liability company, a partnership or a limited liability partnership, or a professional association, if, to be a shareholder, member, or partner, an individual is required to be licensed, certified, or otherwise legally authorized under Title 47 of the



Revised Code to perform the professional service provided by the entity and each such individual is a licensed health professional authorized to prescribe drugs.

NOTE: A physician who practices as a sole proprietor under their medical license is NO LONGER exempt from licensure as a terminal distributor of dangerous drugs if they possess, have custody or control of, and dispense controlled substances containing buprenorphine that are used for the purpose of treating drug dependence or addiction.

For questions regarding these changes, please review the following guidance document. If you need additional information, the most expedient way to have your questions answered will be to e-mail the Board office by visiting: <http://www.pharmacy.ohio.gov/contact.aspx>.

Q1) I am registered opioid treatment program with the Ohio Department of Mental Health and Addiction Services. Do these limits on personally furnishing apply to me?

The following are exempted from restrictions on personally furnishing controlled substances:

(1) Methadone personally furnished to patients for the purpose of treating drug dependence or addiction, if the prescriber meets the conditions specified in 21 C.F.R. 1306.07;

(2) Buprenorphine personally furnished to patients for the purpose of treating drug dependence or addiction as part of an opioid treatment program that possesses a terminal distributor of dangerous drugs license issued under section 4729.54 of the Revised Code, is the subject of a current, valid certification from the substance abuse and mental health services administration of the United States department of health and human services pursuant to 42 C.F.R. 8.11, and meets either of the following criteria:

(a) Buprenorphine and methadone are personally furnished by physicians treating patients participating in the program.

(b) Buprenorphine, but not methadone, is personally furnished by physicians treating patients participating in the program, the program is accredited by a national accrediting organization approved by the substance abuse and mental health services administration, the service of personally furnishing buprenorphine has, notwithstanding section 5119.371 of the Revised Code, been certified by the department of mental health and addiction services under section 5119.36 of the Revised Code, and the program maintains in the record of a patient to whom buprenorphine has been administered or personally furnished a copy of the physician's signed and dated written order for that act.

Q2) What is buprenorphine?

Buprenorphine is a schedule III opioid partial agonist. This means that, although buprenorphine is an opioid, and thus 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. At low doses, buprenorphine enables opioid-addicted individuals to discontinue the misuse of opioids without experiencing withdrawal symptoms. More information on buprenorphine can be accessed here: <http://buprenorphine.samhsa.gov/about.html>.

Q3) What are the most common controlled substances containing buprenorphine that are used to treat drug dependence or addiction?

The most common controlled substances containing buprenorphine that are used to treat drug dependence or addiction include, but are not limited to, the following: buprenorphine/naloxone (Bunavail, Suboxone and Zubsolv) and buprenorphine sublingual tablets (generic Subutex).

Q4) I currently possess, have custody or control of, and distribute controlled substances containing buprenorphine that are used to treat drug dependence or addiction, how do I obtain a license as a terminal distributor of dangerous drugs?

To apply as a terminal distributor of dangerous drugs, please visit:

<http://www.pharmacy.ohio.gov/TDDD/General.aspx> and select the "Application – General Terminal Distributors" link.

Q5) Do I need to submit any additional paperwork with my terminal distributor license application?

All terminal distributor applicants must provide a detailed narrative description of the type of business activities (PLEASE BE SPECIFIC) that will be conducted at the location that requires the applicant to be issued a TDDD license. *The narrative must be on business letterhead, dated and signed by the applicant.* Failure to do so makes your application incomplete, delaying the licensing process.

Q6) I already have a terminal distributor of dangerous drugs license, do I need to submit any additional documentation with my renewal?

No. If you already have a terminal distributor of dangerous drugs license, you do not need to submit any additional information when renewing your license starting in January 2015.

Q7) I am a wholesaler that provides controlled substances containing buprenorphine that are used to treat drug dependence or addiction. Do I need to ensure that the location where I am shipping drugs is licensed as a terminal distributor of dangerous drugs?

Yes. All sites, **INCLUDING physicians who practice as a sole proprietors**, that order controlled substances containing buprenorphine that are used to treat drug dependence or addiction will have to be licensed as a terminal distributor of dangerous drugs. To check the status of an entity ordering controlled substances containing buprenorphine, visit:

<https://license.ohio.gov/lookup/default.asp?division=96>. Failure to do so is a violation rule 4729-9-12 of the Ohio Administrative Code.

Q8) Do the personal furnishing limits apply to prescribers who are veterinarians?

No. Veterinarians are exempted from all limits related to personally furnishing controlled substances.

Q9) I am a prescriber that does not personally furnish controlled substances containing buprenorphine that are used to treat drug dependence or addiction. However, I do personally furnish other controlled substances. Do the restrictions on personally furnishing apply to me?

Yes. A prescriber is prohibited from personally furnishing more than a 72-hour supply or exceeding two thousand five hundred dosage units in a 30-day period for all patients for ANY CONTROLLED SUBSTANCE unless they meet any of the following exemptions:

(1) Methadone provided to patients for the purpose of treating drug dependence or addiction, if the prescriber meets the conditions specified in 21 C.F.R. 1306.07;

(2) Buprenorphine personally furnished to patients for the purpose of treating drug dependence or addiction as part of an opioid treatment program that possesses a terminal distributor of dangerous drugs license issued under section [4729.54](#) of the Revised Code, is the subject of a current, valid certification from the substance abuse and mental health services administration of the United States department of health and human services pursuant to 42 C.F.R. 8.11, and meets either of the following criteria:

(a) Buprenorphine and methadone are personally furnished by physicians treating patients participating in the program.

(b) Buprenorphine, but not methadone, is personally furnished by physicians treating patients participating in the program, the program is accredited by a national accrediting organization approved by the substance abuse and mental health services administration, the service of personally furnishing buprenorphine has, notwithstanding section [5119.371](#) of the Revised Code, been certified by the department of mental health and addiction services under section [5119.36](#) of the Revised Code, and the program maintains in the record of a patient to whom buprenorphine has been administered or personally furnished a copy of the physician's signed and dated written order for that act.

(3) Controlled substances provided to research subjects by a facility conducting clinical research in studies approved by a hospital-based institutional review board or an institutional review board accredited by the association for the accreditation of human research protection programs; and

(4) If the prescriber is a veterinarian licensed under chapter 4741 of the Ohio Revised Code.

Q10) Am I required to report personally furnishing controlled substances to the Ohio Automated Rx Reporting System (OARRS)?

Buprenorphine products personally furnished to patients for the purpose of treating drug dependence or addiction are exempt from reporting those particular products into OARRS, the state's prescription monitoring database.

However, rule 4729-37-03 of the Ohio Administrative Code (<http://codes.ohio.gov/oac/4729-37-03>) states that all prescribers who personally furnish any other controlled substance medications (including buprenorphine products to treat pain) *must* report those medications to OARRS. Reporting, or a "zero report" indicating no dispensing on a particular day, is required on a daily basis. For more information on daily reporting please visit: www.pharmacy.ohio.gov/reporting2.

Q11) What are the penalties for exceeding the limits on personally furnishing controlled substances?

In addition to disciplinary action taken against your professional license, the Ohio State Board of Pharmacy is authorized to impose a fine up to five thousand dollars on a prescriber who fails to

comply with the limits. The Board may impose a separate fine for each instance of failing to comply with the limits on personally furnishing controlled substances.

Q12) I prescribe controlled substances containing buprenorphine that are used to treat drug dependence or addiction. Should I be aware of any other Ohio-specific laws or regulations?

Yes. The Medical Board recently adopted new office-based opioid treatment rules. They can be accessed here: [OAC 4731-11-12](#).

For More Information

Should you need any additional assistance, please do not hesitate to contact the Board by visiting: <http://www.pharmacy.ohio.gov/contact.aspx>.