Requirements for Outpatient Opioid Prescriptions

Updated 4/11/2019

Section 4729.46 of the Ohio Revised Code places the following limitations on the dispensing of outpatient opioid prescriptions:

90-day Supply Limit

The law limits the authority of a pharmacist to dispense an opioid analgesic pursuant to a prescription for a drug to be used on an outpatient basis. It prohibits dispensing or selling more than a 90-day supply of the drug, as determined according to the prescription's instructions for use of the drug, regardless of whether the prescription was issued for a greater amount.

- The limit does not apply to an opioid analgesic that is to be delivered outside this state by mail, parcel post, or common carrier to a patient who resides outside this state.

- The limit does not apply to an opioid medication that is to be used as part of an individual's treatment for opioid dependence or addiction. **NOTE:** Buprenorphine products prescribed to treat pain are subject to the limit.

**NOTE:** The law specifically applies to pharmacists. It does not prohibit a prescriber from writing more than a 90-day supply. Therefore, the enforcement of this provision falls to the dispensing pharmacist.

14-day Prescription Limit

The law generally prohibits a pharmacist from dispensing an opioid analgesic pursuant to a prescription if the drug is to be used on an outpatient basis and more than 14 days have elapsed since the prescription was issued. The law includes the following exceptions:

- A pharmacist may dispense the opioid analgesic after more than fourteen days have elapsed since the prescription was issued if the prescription is one of multiple prescriptions for the drug issued by a single prescriber to the patient on a single day and all of the following apply:
  1. When combined, the prescriptions do not authorize the patient to receive an amount that exceeds a ninety-day supply of the drug, as determined according to the directions for use.
2. The prescriber provided written instructions on the prescription specifying the earliest date on which the prescription may be filled (i.e. “do not fill until”).

3. Not more than 14 days have elapsed since the “do not fill until” date indicated on the prescription. **IMPORTANT:** A specific “do not fill until” date is required.

- A pharmacist may dispense the opioid analgesic after more than fourteen days have elapsed since the prescription was issued if, on the date the prescription was issued, the prescriber issued only one prescription for the drug to the patient and both of the following apply:
  
  1. The prescriber provided written instructions on the prescription specifying the earliest date on which the prescription may be filled (i.e. do not fill until date).
  
  2. Not more than 14 days have elapsed since the “do not fill until” date indicated on the prescription. **IMPORTANT:** A specific “do not fill until” date is required.

- The limit does not apply to refills for opioids analgesics in schedule III - V.

- If the prescription for the opioid analgesic was partially filled within the applicable fourteen-day period (including for those indicating a “do not fill until” date), a pharmacist may dispense the remaining amount of the opioid analgesic after more than fourteen days have elapsed since the prescription was issued. **NOTE:** The dispensing should comply with the partial fill rule.

- The limit does not apply to an opioid analgesic that is to be delivered outside this state by mail, parcel post, or common carrier to a patient who resides outside this state.

- The limit does not apply to an opioid medication that is to be used as part of an individual’s treatment for opioid dependence or addiction. **NOTE:** Buprenorphine products prescribed to treat pain are subject to the limit.

**IMPORTANT:** For the purposes of enforcement, "day" means a calendar day. Therefore, a prescription issued on May 1\textsuperscript{st} is only valid through May 14\textsuperscript{th}.

For questions regarding this provision, please review the following frequently asked questions. 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](http://www.pharmacy.ohio.gov/contact.aspx).
Does the 14-day limit apply to selling an opioid analgesic to a patient (i.e. patient picking up the prescription)?

The law is specific to the dispensing of the opioid analgesic (i.e. prescription is associated with the patient and a final check is conducted). Therefore, if a patient presents a prescription for an opioid analgesic and the pharmacist dispenses an opioid analgesic prescription within 14-days of the date the prescription is issued (or meets any other of the exemptions listed in the beginning of this document), the patient may pick up (i.e. purchase) the opioid analgesic even if the date of pick up exceeds 14 days from the date the prescription was issued.

Does the 14-limit apply to refills for schedule III-V opioid analgesics?

No.

Does the law apply to cough syrups containing codeine or hydrocodone?

Yes. Section 3719.01 of the Ohio Revised Code defines an “opioid analgesic” as a controlled substance that has analgesic pharmacologic activity at the opioid receptors of the central nervous system, including the following drugs and their varying salt forms or chemical congeners:

<table>
<thead>
<tr>
<th>Opioid</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buprenorphine (for pain treatment only)</td>
<td>Schedule III</td>
</tr>
<tr>
<td>Butorphanol</td>
<td>Schedule IV</td>
</tr>
<tr>
<td>Codeine (acetaminophen and other combination products)</td>
<td>Schedule III/V</td>
</tr>
<tr>
<td>Dihydrocodeine/ASA/caffeine</td>
<td>Schedule III</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>Schedule II</td>
</tr>
<tr>
<td>Hydrocodone</td>
<td>Schedule II</td>
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<tr>
<td>Hydrocodone (acetaminophen combination products)</td>
<td>Schedule II</td>
</tr>
<tr>
<td>Hydrocodone (ibuprofen combination products)</td>
<td>Schedule II</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>Schedule II</td>
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<tr>
<td>Meperidine</td>
<td>Schedule II</td>
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<tr>
<td>Methadone</td>
<td>Schedule II</td>
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<tr>
<td>Morphine Sulfate</td>
<td>Schedule II</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>Schedule II</td>
</tr>
<tr>
<td>Oxycodone (acetaminophen, aspirin and other combination products)</td>
<td>Schedule II</td>
</tr>
<tr>
<td>Oxymorphone</td>
<td>Schedule II</td>
</tr>
<tr>
<td>Tapentadol</td>
<td>Schedule II</td>
</tr>
<tr>
<td>Tramadol</td>
<td>Schedule IV</td>
</tr>
</tbody>
</table>
NOTE: Pursuant to a Board resolution adopted on April 4, 2017, the Board does not consider a controlled substance medication utilized as an antidiarrheal to be classified as an “opioid analgesic” for the purposes of enforcing this provision of law.

The prescription was written by an out-of-state prescriber. Am I required to adhere to the requirements of the law?

Yes. Unless, the pharmacist is dispensing an opioid analgesic to be delivered outside of this state by mail, parcel post, or common carrier to a patient who resides outside of Ohio.

Does the 90-day supply include the initial fill and refills?

The 90-day supply restriction applies to what is dispensed to a patient at one time. If a patient presents with a 90-day prescription for tramadol with two refills, then the pharmacist may dispense the initial 90-day supply as well as subsequent refills because each individual dispensing cannot exceed a 90-day supply.

As a reminder, pharmacists should use their professional judgement when a patient makes a request for early refills. This may allow a patient to stockpile medication.

If the prescription is written for more than 90 days, can I only fill 90 days’ worth of medication? Am I required to contact the prescriber to let them know of the doses that are being forfeited?

The pharmacist may only dispense 90-days’ worth of opioid analgesics regardless of what is written on the prescription. For example, only 90-days of oxycodone may be dispensed for a prescription presented for a 120-day supply. Following the dispensing of the 90- day supply, that prescription is no longer valid (i.e. the patient cannot return for the remaining 30-day supply).

It is up to the pharmacist’s professional judgement whether to contact the prescriber. However, the change should be communicated to the patient.

Are opioid partial agonists (buprenorphine) used for the treatment of opioid dependence or addiction impacted by this law?

No. The law exempts these medications if being used to treat opioid dependence or addiction. Buprenorphine that is used for the treatment of pain would be subject to this law.
**Will the opioid prescription limits impact inpatients of an institutional facility?**

No. The law specifically states the limits apply to opioid prescriptions dispensed on an outpatient basis. Rule 4729-17-01 of the Administrative Code defines inpatient as any person who receives drugs for use while within the institutional facility.

An institutional facility means a hospital as defined in section 3727.01 of the Revised Code, or a facility licensed by the Ohio state board of pharmacy and the Ohio department of health, the Ohio department of rehabilitation and correction, the Ohio department of developmental disabilities, or the Ohio department of mental health and addiction services at which medical care is provided on site and a medical record documenting episodes of care, including medications ordered and administered, is maintained, including but not limited to:

- Convalescent homes;
- Developmental facilities;
- Long-term care facilities;
- Nursing homes;
- Psychiatric facilities;
- Rehabilitation facilities;
- Developmental disability facilities;
- Level III sub-acute detoxification facilities; and
- Jails and correctional facilities.

**Do the restrictions in the law apply to prescriptions for compounded products containing opioid analgesics?**

Yes.

**Can the issue date of the prescription be changed by the pharmacist after consultation with and agreement of the prescriber?**

Yes. If a prescriber authorizes a change of the issue date, then the prescription may be dispensed if it is within 14 days of new issue date.

For schedule III-V prescriptions, an agent of the prescriber may authorize the change of issue date.