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New Requirements for Opioid Prescriptions – Effective 4.6.2017

Updated 6-21-2017

On January 4, 2017, SB 319 was signed by Governor Kasich. This law (effective 4/6/2017) includes the following provisions as they relate to **outpatient prescriptions** for opioid analgesics:

14-day Prescriptions for Opioid Analgesics: The law generally prohibits a pharmacist, pharmacy intern, or terminal distributor 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.

PLEASE BE ADVISED: *The 14-day limit only applies to the filling of the initial opioid analgesic prescription (schedule II-V).* ***The Board does not interpret the 14-day limit to apply to refills of schedule III-V opioid analgesics.*** *(See Board Resolution at the end of this document).*

90-day Supply: The law limits the authority of a pharmacist, pharmacy intern, or terminal distributor of dangerous drugs to dispense or sell 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.

These provisions are set to take effect on **April 6, 2017**.

Please note: The law specifically applies to pharmacists, interns and pharmacies. It does not prohibit a prescriber from writing more than a 90-day supply. Therefore, the enforcement of this provision falls to the pharmacist, intern and pharmacy. The 90- day supply provision also applies to veterinarians who may also personally furnish more than a 72-hour supply of opioid analgesics from their offices.

For questions regarding these changes, 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.

For a summary of SB 319, please visit: https://www.legislature.ohio.gov/download?key=6079&format=pdf

(1) Does the 14-day limit apply to selling an opioid analgesic to a patient (i.e. patient picking up the prescription)? (UPDATED)

Pursuant to a Board resolution adopted on March 7, 2017, the Board has determined that a pharmacist or terminal distributor is permitted to sell an opioid analgesic if the prescription was presented to and dispensed by a pharmacist (i.e. prescription is associated with the patient and a final check is conducted) within 14-days of the date the prescription was issued. A copy of the Board resolution can be found at the end of this document.

Therefore, if a patient presents a prescription for an opioid analgesic and the pharmacist dispenses (i.e. fills) an opioid analgesic prescription within 14-days of the date the prescription is issued, 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.

For the purposes of enforcement, "day" means a calendar day. Therefore, a prescription issued on May 1, 2017 is only valid through May 14, 2017.

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

No. Pursuant to a Board resolution adopted on March 7, 2017, the Board has determined that the 14-day limit only applies to the filling of the initial opioid analgesic prescription (schedule II- V). The Board does not interpret the 14-day limit to apply to refills of schedule III-V opioid analgesics. A copy of the Board resolution can be found at the end of this document.

(3) A prescription for an opioid analgesic was issued before the law change went into effect (April 6, 2017). Do I still have to fill within 14 days of the date issued?

No. You would follow the requirements for dispensing opioid analgesic prescriptions prior to the law change.

(4) 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:

Opioid	Schedule
Butorphanol	Schedule IV
Codeine (acetaminophen and other combination products)	Schedule III/V
Dihydrocodeine/ASA/caffeine	Schedule III
Fentanyl	Schedule II
Hydrocodone	Schedule II
Hydrocodone (acetaminophen combination products)	Schedule II
Hydrocodone (ibuprofen combination products)	Schedule II
Hydromorphone	Schedule II
Meperidine	Schedule II
Methadone	Schedule II
Morphine Sulfate	Schedule II
Oxycodone	Schedule II
Oxycodone (acetaminophen, aspirin and other combination products)	Schedule II
Oxymorphone	Schedule II
Tapentadol	Schedule II
Tramadol	Schedule IV

NOTE: Pursuant to a Board resolution adopted on April 4, 2017, the Board does not consider the following to be classified as an "opioid analgesic" for the purposes of enforcing this requirement:

1. Buprenorphine products used for the treatment of opioid dependence or addiction; or
2. A controlled substance medication utilized as an antidiarrheal.

A copy of the resolution can be found at the end of this document.

(5) Are there any exceptions to the law?

Pharmacies and pharmacists that dispense or sell an opioid analgesic to be delivered outside of this state by mail, parcel post, or common carrier to a patient who resides outside of this state are exempted from these requirements.

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

Yes. Unless, the pharmacy or 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.

(7) Does the 14-day limit for an opioid analgesic prescription impact the practice of issuing multiple concurrent prescriptions for schedule II opioid analgesics? (UPDATED)

The law preserves the right to continue to issue multiple concurrent prescriptions for schedule II opioid analgesics if all the following apply:

(1) The prescriber has provided written instructions indicating the earliest date on which the prescription may be filled;

(2) The prescription is one of multiple prescriptions for the opioid analgesic issued by the prescriber to the patient on a single day;

(3) When combined, the prescriptions do not authorize the patient to receive more than a 90- day supply of the opioid analgesic.

NOTE: A prescription that satisfies these conditions may be dispensed until 14 days have elapsed since the date indicated on the prescription as the earliest date on which it may be filled. (For example, an opioid analgesic prescription that has a "do not fill until" date of 5/1/2017 is valid through 5/14/2017 – *this includes the initial prescription*). It is recommended that prescribers indicate the number of prescriptions issued in the series (for example, "1 of 3").

For the purposes of enforcement "day" means a calendar day. Therefore, a prescription issued on May 1, 2017 is only valid through May 14, 2017.

IMPORTANT: A specific "do not fill until" date is required.

(8) 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.

(9) 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, intern or pharmacy may only fill 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.

(10) The prescription was written before the law went into effect (April 6, 2017). Am I still required to adhere to the 90-day supply limit?

No. You would follow the requirements for these prescriptions prior to the law change.

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

No. Pursuant to a Board resolution adopted on April 4, 2017, the Board does not consider buprenorphine products used for the treatment of opioid dependence or addiction to be an "opioid analgesic" for the purposes of enforcing this requirement. A copy of the resolution can be found at the end of this document.

(12) Will the 14-day limit apply to patients receiving partial fill prescriptions of schedule II opioid analgesics in accordance with rule 4729-5-26 of the Ohio Administrative Code?

If the initial fill of the prescription is dispensed within 14-days of the date it was issued, then it will not impact outpatient partial fill prescriptions dispensed in accordance with rule 4729-5-26. The Board addressed this issue in a March 7, 2017 resolution that can be found at the end of this document.

If the patient is in an institutional facility, including a long-term care facility, please refer to the next question.

(13) 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:

(1) Convalescent homes;
(2) Developmental facilities;
(3) Long-term care facilities;
(4) Nursing homes;
(5) Psychiatric facilities;
(6) Rehabilitation facilities;
(7) Developmental disability facilities;
(8) Level III sub-acute detoxification facilities; and
(9) Jails and correctional facilities.

(14) Do the restrictions in the law apply to prescriptions for compounded products containing opioid analgesics?

Yes.

(15) Can the issue date of the prescription be changed by the pharmacist after consultation with and agreement of the prescribing practitioner?

Yes. Current Board policy states the following as it relates to pharmacist changes of controlled substance prescriptions:

> *The pharmacist may add or change the patient's address upon verification. The pharmacist may add or change the dosage form, drug strength, drug quantity, directions for use, or issue date only after consultation with and agreement of the prescribing practitioner. Such consultations and corresponding changes should be noted by the pharmacist on the prescription. Pharmacists and practitioners must comply with any state/local laws, regulations, or policies prohibiting any of these changes to controlled substance prescriptions. The pharmacist is never permitted to make changes to the patient's name, controlled substance prescribed (except for generic substitution permitted by state law) or the prescriber's signature.*

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.

(16) Is a prescriber permitted to put a "do not fill until" date on a single opioid prescription and does the 14-day limit apply? (UPDATED)

As stated in the law, the 14-day limit applies to the issue date of a single prescription of an opioid analgesic even if it has a "do not fill until" date. For example, a person who receives a single prescription prior to a surgical procedure.

However, the limit applies to the "do not fill until" date for multiple concurrent prescriptions as outlined in Q7 of this document ***(including the initial prescription)***. For example, a chronic pain patient receiving multiple concurrent prescriptions.

The Board is working to potentially clarify this issue and will issue additional guidance if any changes are made.

Resolution: 14-Day Limit on Opioid Analgesic Prescriptions

Adopted March 7, 2017

The State of Ohio Board of Pharmacy hereby recognizes the following, as it applies to section 4729.45 of the Ohio Revised Code enacted by Ohio SB 319 (131st General Assembly):

- The 14-day limit on dispensing an opioid analgesic applies only to the initial or first fill of the prescription. It does not apply to refills of schedule III - V opioid analgesics.

- The limit set forth in division (B)(2) of section 4729.45 does not prohibit the following:

    - The selling of an opioid analgesic if the prescription was presented and dispensed by a pharmacist (i.e. prescription is associated with patient and a final check is conducted) within 14-days of the date the prescription was issued.

    - The selling or dispensing of partial fills of schedule II opioid analgesics pursuant to rule 4729-5-26 of the Ohio Administrative Code, if the initial dispensing of the prescription occurs within 14-days of the date the prescription was issued.

Resolution: Definition of Opioid Analgesic

Adopted April 4, 2017

For the purposes of enforcing section 4729.46, the Board hereby acknowledges that an opioid analgesic does not include a controlled substance medication utilized as an antidiarrheal.

For the purposes of enforcing section 4729.46, the Board hereby acknowledges that an opioid analgesic does not include medications containing buprenorphine that are used for the treatment of opioid dependence or abuse, as indicated on the product's labeling.