



# Members Brief

An informational brief prepared by the LSC staff for members and staff of the Ohio General Assembly

Author: Elizabeth Molnar, Attorney  
Reviewer: Laurel Mannion, Division Chief

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## Opioid Prescribing

The General Assembly has enacted laws to address the opioid crisis, including by providing for limits on the quantity and potency of opioids prescribed to treat pain, requiring an opioid prescriber to first review patient information in the Ohio Automated Rx Reporting System (OARRS), and broadening access to naloxone, a prescription drug used to reverse an opioid overdose.

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### Opioid overdose deaths

From 1999 to 2020, across the United States, more than 564,000 people died from overdoses involving an opioid, including prescription and illicit opioids.<sup>1</sup> In 2020 alone, nearly 75% of the 91,799 drug overdose deaths involved an opioid.<sup>2</sup> The federal Centers for Disease Control and Prevention (CDC) report that over 104,034 drug overdose deaths occurred in the

<sup>1</sup> See [Opioid Data Analysis and Resources](#), which is available on the Centers for Disease Control and Prevention’s website: [cdc.gov](https://www.cdc.gov)

<sup>2</sup> See [Understanding the Opioid Overdose Epidemic](#), which is available on the Centers for Disease Control and Prevention’s website: [cdc.gov](https://www.cdc.gov).

United States in the twelve months ending in February 2022.<sup>3</sup> According to the CDC, synthetic opioids – including illicitly manufactured fentanyl – are the main driver of these deaths.<sup>4</sup>

When considered by state, Ohio often ranks near the top of overdose death rates, having experienced 4,251 drug overdose deaths in 2019, a rate of 38.3 per 100,000 population, the third highest in the nation.<sup>5</sup> And in 2020, Ohio suffered 5,017 unintentional drug overdose deaths, a 25% increase over the number of overdose deaths in 2019, with May 2020 having the highest number of deaths per month ever recorded in Ohio (574 deaths).<sup>6</sup> Of those deaths, fentanyl was involved in 81%. Note, however, that the percentage of overdose deaths involving natural and semisynthetic opioids (e.g., oxycodone) decreased from 2019 to 2020.<sup>7</sup>

The rise in opioid overdose deaths can be characterized by three distinct waves. The first, in the 1990s, involved increased prescribing of semisynthetic opioids like oxycodone and hydrocodone and their resulting overdose deaths. The second, beginning in 2010, saw rapid increases in overdose deaths involving illegal heroin. The third, beginning in 2013, has been marked by significant increases in overdose deaths involving synthetic opioids, such as fentanyl. The legislative efforts described in this brief address prescription opioids.

## **Review of patient information in the Ohio Automatic Rx Reporting System (OARRS)**

Established in 2006, OARRS is the drug database maintained by the State Board of Pharmacy.<sup>8</sup> Patient information from the database, including information from other states, is available to prescribers and pharmacists to determine if patients are misusing or diverting certain drugs, including opioids.<sup>9</sup> Under rules adopted by the Board, when an opioid is dispensed by a pharmacy or personally furnished by a prescriber to an outpatient, this information must be reported to OARRS within 24 hours of the opioid being dispensed or furnished.<sup>10</sup>

Since 2015,<sup>11</sup> Ohio statutory law requires a physician, physician assistant, advanced practice registered nurse, and dentist – before first prescribing an opioid for a patient – to request

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<sup>3</sup> See [Provisional Drug Overdose Death Counts](#), which is available on the CDC’s National Center for Health Statistics, National Vital Statistics System’s website: [cdc.gov/nchs/nvss](https://www.cdc.gov/nchs/nvss).

<sup>4</sup> See [Overdose Deaths Accelerating During COVID-19](#), which is available on the CDC’s website: [cdc.gov/media](https://www.cdc.gov/media).

<sup>5</sup> See [Death Rate Maps & Graphs](#), which is available on the CDC’s website, [cdc.gov](https://www.cdc.gov), keyword search “overdose.”

<sup>6</sup> See [Ohio Monthly Overdose Preliminary Data Summary, April 2022](#), which is available on the Ohio Department of Health’s website: [odh.ohio.gov/know-our-programs](https://www.odh.ohio.gov/know-our-programs).

<sup>7</sup> See [2020 Ohio Drug Overdose Report](#), which is available on the Ohio Department of Health’s website: [odh.ohio.gov/know-our-programs](https://www.odh.ohio.gov/know-our-programs).

<sup>8</sup> R.C. 4729.75.

<sup>9</sup> R.C. 4729.80.

<sup>10</sup> Ohio Administrative Code (O.A.C.) 4729:8-3-04.

<sup>11</sup> H.B. 341, enacted by the 130<sup>th</sup> General Assembly.

patient information from OARRS that covers at least the previous 12 months.<sup>12</sup> This requirement does not apply, though, if the opioid is prescribed for less than seven days.

Along with making an initial request, the prescriber may be required to make further requests for patient information from OARRS if the patient's course of treatment with the opioid continues for more than 90 days. The prescriber must do so at intervals of at least 90 days and until the course of treatment ends.<sup>13</sup>

### **Exceptions to OARRS requests**

A prescriber is not required to review patient information in OARRS if an OARRS report is not available or if the opioid is prescribed under the following circumstances:

- For a hospice patient or any other patient who has been diagnosed as terminally ill;
- For the treatment of cancer or another condition associated with cancer;
- For administration in a hospital, nursing home, or residential care facility;
- To treat pain resulting from a surgical or other invasive procedure or a delivery.

### **Prescribing opioids for minor patients**

Since 2014, Ohio statutory law has imposed conditions on prescribing an opioid in a single course of treatment for a minor patient.<sup>14</sup> These conditions include assessing the minor for mental health or substance use disorders, determining whether the minor is taking (or has taken) drugs for such disorders, discussing the risks of addiction and overdose with the minor and minor's parent, and obtaining and recording the parent's written consent to treatment with an opioid. In recording the consent, the prescriber must use the [Start Talking! Consent form \(PDF\)](#), a form separate from any other document the prescriber uses to obtain consent to treatment for minors, available on the State Medical Board's website, [med.ohio.gov](http://med.ohio.gov). The Start Talking! Form is required to include the opioid's name, amount, and quantity, statements that the opioid has the potential for abuse and that the prescriber discussed its risks with the minor and minor's parent, the number of refills, and the minor parent's signature. Note that these conditions do not apply in all circumstances, including when a minor receives treatment in a hospital, emergency facility, or ambulatory surgical facility.

### **Opioid prescribing limits**

In addition to requiring OARRS requests and establishing certain conditions when prescribing for minors, Ohio law sets other conditions on prescribers when treating pain with opioids, including by establishing limits on the quantity and potency of opioids that may be prescribed. (An opioid's potency can be measured by its morphine equivalent daily dose, or MED.) These limits and conditions depend, however, on the type of pain being treated – acute, subacute, or chronic pain.

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<sup>12</sup> R.C. 4715.302(B)(1), 4723.487(B)(1), 4725.092(B)(1), 4730.53(B)(1), and 4731.055(B)(1).

<sup>13</sup> R.C. 4715.302(B)(2), 4723.487(B)(2), 4725.092(B)(2), 4730.53(B)(2), and 4731.055(B)(2).

<sup>14</sup> R.C. 3719.061.

## **Authority to establish prescribing limits and conditions**

Ohio statutory law recognizes the authority of a physician to treat chronic pain with opioids and requires the State Medical Board to adopt rules establishing standards and procedures for treatment. But statutory law does not set any limits on the quantity and potency that may be prescribed to treat chronic pain.<sup>15</sup> Neither does it specifically address the prescribing of opioids for acute and subacute pain. Instead, since 2017, Ohio law has authorized a “health-related licensing board,” or a board responsible for licensing prescribers, to adopt rules limiting the amount of an opioid that may be prescribed under a single prescription.<sup>16</sup>

It was under this authority that the State Medical Board, Board of Nursing, and State Dental Board each adopted rules in 2017 establishing limits on the treatment of acute pain with prescription opioids.<sup>17</sup> The boards later established conditions on physicians, advanced practice registered nurses, and dentists who prescribe opioids to treat subacute and chronic pain.<sup>18</sup>

Because the Medical, Dental, and Nursing Board rules governing the treatment of pain with opioids are largely the same, this brief primarily focuses on the rules governing physician prescribing.

## **Types of pain – acute, subacute, and chronic**

Although Medical Board rules and statutory law neither define nor describe acute pain, the Nursing Board and Dental Board define it as pain that normally fades with healing, is related to tissue damage, significantly alters a patient’s typical function, and is expected to be time-limited and not more than six weeks in duration.<sup>19</sup>

While not specifically addressed in statutory law, “subacute pain” is defined in a Medical Board rule as pain that has persisted after reasonable medical efforts have been made to relieve it and that continues either episodically or continuously for 6-12 weeks following the initial onset of pain. “Subacute pain” may be the result of underlying medical disease or condition, injury, medical or surgical treatment, inflammation, or unknown cause.<sup>20</sup>

In contrast, chronic pain lasts more than 12 weeks. The Revised Code defines “chronic pain” as pain that has persisted after reasonable medical efforts have been made to relieve the pain or cure its cause and that has continued, either continuously or episodically, for longer than three continuous months. “Chronic pain” does not include pain associated with a terminal condition or with a progressive disease that, in the normal course of progression, may reasonably be expected to result in a terminal condition.<sup>21</sup>

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<sup>15</sup> R.C. 4731.052.

<sup>16</sup> R.C. 3719.062 (enacted in S.B. 319, 131<sup>st</sup> General Assembly).

<sup>17</sup> O.A.C. 4715-6-02, 4723-9-10, and 4731-11-13.

<sup>18</sup> O.A.C. 4715-6-03, 4723-9-10, and 4731-11-14.

<sup>19</sup> O.A.C. 4715-6-03, 4723-9-10, and 4731-11-13.

<sup>20</sup> O.A.C. 4731-11-01.

<sup>21</sup> R.C. 4731.052.

## **Acute pain prescribing limits**

The Medical Board prohibits a physician from prescribing extended-release or long-acting opioids for a patient's acute pain. Additionally, a physician must consider nonopioid treatment options for a patient's acute pain.

If a physician determines that opioids are required to treat acute pain – based on the patient's history and a physical examination – the physician is required to prescribe the minimum quantity and potency necessary for the expected duration of the pain, generally presumed to be not more than a three-day supply. With respect to an opioid's potency, current law generally restricts the MED to an average of 30 per day.

While a three-day supply is clearly preferred under the rule, it also establishes upper limits on the amount that may be prescribed for acute pain – for an adult patient, not more than a seven-day supply and for a minor patient, not more than a five-day supply.

A physician may prescribe an opioid for a longer duration if the pain is expected to persist for more than seven days (or five days in the case of a minor patient) and the physician documents the reasons for exceeding that limit in the patient's medical record. A physician also may exceed the 30 MED limit if the patient suffers from conditions of such severity that pain cannot be managed within the 30 MED limit, the physician determines that exceeding the limit is necessary based on the physician's clinical judgment and the patient's needs, and the physician documents this information in the patient's medical record.<sup>22</sup>

### **Exceptions**

Ohio law specifies that the general limits on the amount and potency of an opioid prescribed for acute pain do not apply when prescribing the drug to a patient who is receiving hospice or palliative care, has been diagnosed with a terminal condition, is receiving inpatient care, has cancer or another condition associated with the patient's cancer, or is receiving medication-assisted treatment for opioid addiction.

### **Subacute and chronic pain**

Rather than set outright limits on the quantity or potency of opioids, the subacute and chronic pain rule instead establishes conditions that a physician must meet when prescribing opioids to treat these types of pain.<sup>23</sup> For instance, before prescribing, the physician must document in the patient's medical record assessment activities to assure the appropriateness and safety of the medication. These activities include development of a treatment plan for the patient (which must consist of a diagnosis, the goals for treatment, the rationale for the medication choice and dosage), the planned duration of treatment, and steps for further assessment and follow-up.<sup>24</sup>

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<sup>22</sup> O.A.C. 4731-11-13.

<sup>23</sup> O.A.C. 4731-11-14.

<sup>24</sup> O.A.C. 4731-11-14(B).

Under the current rule, the number of conditions on the physician's treatment grows as the physician begins to increase an opioid's potency, or MED. For example, when the potency reaches 50 MED per day, the physician must update the initial patient assessment, update or formulate a new treatment plan, and obtain written informed consent.<sup>25</sup> And before increasing the dosage to 80 MED per day or greater, the physician must generally do the following:

- Enter into a written treatment plan agreement with the patient, which may require drug screens, pill counts, and drug tapering;
- Offer a prescription for naloxone; and
- If the physician is neither a specialist in the area of the body affected by the pain nor a pain management specialist, either consult with such a specialist or, if certain aberrant behavior is present, a specialist in addiction medicine or psychiatry or obtain a medication therapy management review.<sup>26</sup>

The rule specifically prohibits a physician from prescribing a dosage that exceeds 120 MED per day, unless any of the following apply:

- The physician holds board certification in pain medicine or hospice or palliative care;
- The physician has received a written recommendation for a dosage exceeding an average of 120 MED per day from a physician board-certified in pain medicine or hospice and palliative care who based that recommendation on a face-to-face visit and examination of the patient; or
- The patient was receiving an average daily dose of 120 MED or more before the rule's effective date (December 23, 2018).<sup>27</sup>

But even in the case of a patient who was receiving an average of 120 MED or more per day before the rule's effective date, the patient still must satisfy the face-to-face visit and examination requirement.<sup>28</sup>

## **Naloxone access**

Naloxone, also known as Narcan, is a prescription drug used to reverse overdoses from opioids like heroin, morphine, and oxycodone.<sup>29</sup> Recent General Assemblies have enacted laws to increase access to this drug.<sup>30</sup> For example, a prescriber may now issue a nonpatient a specific

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<sup>25</sup> O.A.C. 4731-11-14(C).

<sup>26</sup> O.A.C. 4731-11-14(D).

<sup>27</sup> O.A.C. 4731-11-14(E).

<sup>28</sup> O.A.C. 4731-11-14(E)(3).

<sup>29</sup> Substance Abuse and Mental Health Services Administration, [Naloxone](https://www.samhsa.gov), available at [samhsa.gov](https://www.samhsa.gov), keyword search "Naloxone."

<sup>30</sup> H.B. 193, enacted by the 134<sup>th</sup> General Assembly and effective September 23, 2022, replaced references to naloxone found in the Revised Code with the term "overdose reversal drug," defined to mean naloxone

prescription for naloxone to and in the name of a family member, friend, or person in a position to assist an individual at risk of experiencing an opioid-related overdose.<sup>31</sup>

In 2015, the General Assembly authorized the creation of protocols for dispensing naloxone without a prescription. In accordance with a protocol developed by a physician or local board of health, a pharmacist or pharmacy intern may dispense naloxone without a prescription to either:

1. An individual who there is reason to believe is experiencing or at risk of experiencing an opioid-related overdose; or
2. A family member, friend, or other person in a position to assist such an individual.<sup>32</sup>

The law grants qualified immunity from criminal prosecution to family members, friends, and individuals in a position to assist with an overdose who obtain naloxone and administer it in accordance with the provisions described above.<sup>33</sup>

Additionally, Ohio law provides peace officers qualified immunity from administrative action, criminal prosecution, and liability for civil damages related to the administration of naloxone to an individual who is apparently experiencing an opioid-related overdose.<sup>34</sup> The State Board of Pharmacy specifically exempts law enforcement agencies and peace officers from the requirement to be licensed as a terminal distributor of dangerous drugs when possessing naloxone in such cases.<sup>35</sup> According to the Board, this exemption permits law enforcement agencies to purchase naloxone from wholesalers and other terminal distributors without a license from the Board.<sup>36</sup>

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and any other drug approved for the reversal of an opioid-related overdose. See [LSC Final Analysis for H.B. 193 \(PDF\)](#), which is available on the General Assembly's website: [legislature.ohio.gov](http://legislature.ohio.gov).

<sup>31</sup> R.C. 2925.61, 4723.488, 4729.01(H), 4730.431, and 4731.94.

<sup>32</sup> R.C. 4729.44(B).

<sup>33</sup> R.C. 2925.61(B).

<sup>34</sup> R.C. 2925.61(E).

<sup>35</sup> R.C. 4729.541(A)(11).

<sup>36</sup> Ohio Board of Pharmacy, [Law Enforcement Agencies Seeking to Obtain Naloxone Hydrochloride \(Narcan®\) \(PDF\)](#), which is available on the Board's website, [pharmacy.ohio.gov](http://pharmacy.ohio.gov), click on Law Enforcement, then Law Enforcement Guidance Document.