



## HARM REDUCTION AND OVERDOSE PREVENTION Fact Sheet

# Naloxone Prescription Mandates

## Background

Drug overdose continues to claim the lives of tens of thousands of people in the United States every year - over 67,000 in 2018 alone.<sup>1</sup> Opioids, both prescription painkillers and street drugs such as heroin and illicitly manufactured fentanyl, were responsible for approximately 70% of these deaths.<sup>2</sup> Naloxone, a pure opioid antagonist, displaces opioids from the receptors to which they attach, quickly and effectively reversing opioid overdose before it can become fatal.<sup>3</sup> Nearly every person who died of a witnessed opioid overdose could have been saved if the other person or people present had naloxone with them.

Despite significant legal and financial barriers that continue to inhibit the initiation and efficient operation of community-based harm reduction organizations, harm reductionists distributed over one million doses of naloxone in 2019.<sup>4,5</sup> The distribution of naloxone by these organizations, which provide the medication directly to individuals at high risk of overdose or to their friends, family, and community members, has likely saved tens of thousands of lives and should be a top priority for naloxone distribution. Many individuals who receive naloxone from these organizations may be unable or unwilling to obtain naloxone from a pharmacy due to social stigma, lack of transportation, and financial barriers.

While the proportion of opioid-related overdoses attributable to pharmacy-obtained opioids has fallen with the decrease in prescription of those opioids, they still account for a large number of opioid-related fatalities.<sup>6</sup> It is therefore reasonable to supplement community naloxone distribution with pharmacy-based naloxone access targeted at those individuals who may be at heightened risk of opioid-related overdose. Both the Department of Health and Human Services generally and the Centers for Disease Control and Prevention specifically recommend that naloxone be prescribed to such individuals.<sup>7,8</sup> Despite repeatedly failing to make naloxone available over-the-counter, which would remove most legal barriers that deny individuals access to this lifesaving medication, the Food and Drug Administration now requires that the labels of opioid medications recommend that prescribers discuss naloxone with patients when prescribing those medications.<sup>9,10</sup>

While many states also recommend that naloxone be prescribed in certain circumstances, some have gone further and now require that naloxone be prescribed or offered to some patients.<sup>11</sup> This brief fact sheet describes those requirements and provides links to the text of the relevant laws.



## Naloxone prescribing mandates

As of September 30, 2020, ten states have enacted laws or regulations that require certain medical professionals to prescribe or offer a prescription for naloxone to some individuals under their care. In two states (CA and OH) prescribers are only required to offer a prescription for naloxone, while in eight (AZ, FL, NJ, NM, RI, VA, VT, WA) they are required to provide a prescription for the medication. There does not appear to be a clear geographic or temporal trend in adoption of these laws, and they have been passed in both “red” and “blue” states. There also does not appear to be a clear acceleration in the enactment of these laws over time:

**2017:** VA, VT

**2018:** AZ, FL, OH, RI, WA

**2019:** CA, NM

**Through Sept. 2020:** NJ

The circumstances that trigger these requirements vary by state. While most require naloxone to be prescribed or offered when opioids over a certain Morphine Milligram Equivalent (MME) are prescribed, this is not always the case. Florida’s requirement, for example, applies any time a schedule II opioid is prescribed for the treatment of pain related to a traumatic injury with an Injury Severity Score of 9 or greater, and New Mexico’s requirement applies where five days or more of an opioid are prescribed. Where an MME requirement is present, the triggering level varies from 50 in Ohio and Rhode Island to 120 in Virginia.

Most states also require naloxone to be prescribed or offered where the patient meets another criterion for being at increased risk of overdose, such as a history of substance use disorder, even where the opioid prescribed does not meet the MME threshold. In all states but Washington, which requires a naloxone prescription to be confirmed or provided for all high-risk patients, the requirements are triggered only when the provider is issuing a prescription for opioids.<sup>12</sup>

Unlike with laws governing the operation of pain clinics, none of these laws provide clear penalties for non-compliance. Only one discusses penalties specific to failing to follow the prescribing mandate. In that state, California, a prescriber who fails to comply with the requirements “shall be referred to the appropriate licensing board solely for the imposition of administrative sanctions deemed appropriate by that board.”<sup>13</sup> It is presumed that, in most states, failure to comply with the mandate would similarly be a matter for the licensing board that regulates the relevant provider.<sup>14</sup>

Table 1 provides a brief overview of these laws. Unless otherwise noted, where different requirements apply to different medical professionals Table 1 lists requirements applicable to physicians. Appendix 1 provides a more detailed explanation of these laws, including the date at which they were signed or approved, if different than the effective date. It also lists where the requirements were changed over time, as happened in California and Vermont, and any differences applicable to non-physician prescribers.

**Table 1: Overview of laws that mandate naloxone prescribing**

State	Effective date	Requirement	Brief explanation
<a href="#">Arizona</a>	April 25, 2018	Prescribe	Law requires the co-prescribing of naloxone by “prescribing health professional” when: <ul style="list-style-type: none"><li>the patient is issued a new prescription for a schedule II opioid that is greater than 90 MME per day AND</li></ul>



			<ul style="list-style-type: none"> <li>the prescription is to be filled or dispensed outside of a health care institution.</li> </ul>
<a href="#">California</a>	January 1, 2019	Offer	<p>Prescriber (not including veterinarians, those prescribing within the corrections department, when ordering medication to be administered in the inpatient or outpatient setting, or to a patient that is terminally ill) is required to offer a prescription for (but not necessarily prescribe) naloxone to a patient who is either:</p> <ul style="list-style-type: none"> <li>receiving 90 MME or higher per day; OR</li> <li>receiving any opioid concurrently with any benzodiazepine; OR</li> <li>at increased risk of overdose, “including a patient with a history of overdose, a patient with a history of substance use disorder, or a patient at risk for returning to a high dose of opioid medication to which the patient is no longer tolerant.”</li> </ul>
<a href="#">Florida</a>	July 1, 2018	Prescribe	When a schedule II opioid is prescribed for the treatment of pain related to a traumatic injury with an Injury Severity Score of 9 or greater, naloxone must be prescribed.
<a href="#">New Jersey</a>	May 21, 2020	Prescribe	When controlled dangerous substances are continuously prescribed for management of chronic pain, a practitioner of medicine, dentistry, optometry, or nursing (by an Advanced Practice Nurse) must provide a prescription for an opioid antidote if the patient has one or more prescriptions totaling 90 morphine milligram equivalents or more per day, or is concurrently obtaining an opioid and a benzodiazepine. Requirement currently expires when the state COVID-19 public health emergency ends.
<a href="#">New Mexico</a>	June 14, 2019	Prescribe	Health care provider who prescribes, distributes, or dispenses an opioid analgesic to a patient for the first time must advise on risks and inform the patient of the availability of opioid antagonist. Additionally, they must prescribe naloxone when prescribing a five day supply or greater of opioid analgesics.
Ohio <a href="#">(physician)</a> <a href="#">(APRN)</a>	December 23, 2018	Offer	<p>When treating subacute or chronic pain with an opioid analgesic, physician or advanced practice registered nurse “shall offer” a prescription for naloxone to a patient receiving an opioid analgesic prescription under any of the following circumstances:</p> <ul style="list-style-type: none"> <li>The patient has a history of prior opioid overdose; OR</li> <li>The dosage prescribed exceeds a daily average of eighty MED (Morphine Equivalent Dose); OR</li> <li>The patient is co-prescribed a benzodiazepine, sedative hypnotic drug, carisprodal, tramadol, or gabapentin; OR</li> <li>The patient has a concurrent substance use disorder.</li> </ul> <p>When the daily opioid dosage averages fifty MED or greater (for APRNs, only where the dosage exceeds 50 MED) the provider “shall consider offering” a prescription for naloxone.</p>
<a href="#">Rhode Island</a>	July 2, 2018	Prescribe	Prescriber must co-prescribe naloxone when:



			<ul style="list-style-type: none"> <li>• Prescribing an opioid to a patient who is receiving 50 MME or greater – or document in the medical record why co-prescribing is not appropriate for the patient; OR</li> <li>• Prescribing any dose of an opioid when a benzodiazepine has been prescribed in the past thirty days, or will be prescribed at the visit. Prescriber also required to note medical necessity of the co-prescription of the opioid and the benzodiazepine and explain why the benefit outweighs the risk; OR</li> <li>• Prescribing any dose of an opioid to a patient with a prior history of opioid use disorder or overdose. Prescribers must also note medical necessity of prescribing of the opioid and explain why the benefit outweighs the risk given the patient’s previous history.</li> </ul>
<a href="#">Virginia (physicians)</a> <a href="#">(dentists)</a>	March 15, 2017 (emergency regulation); August 8, 2018	Prescribe	“Naloxone shall be prescribed for any patient when risk factors of prior overdose, substance abuse, doses in excess of 120 MME/day, or concomitant benzodiazepine is present,” including when prescribed by dentists.
<a href="#">Vermont</a>	July 1, 2017	Prescribe	Prescribers required to co-prescribe naloxone for patients who: <ul style="list-style-type: none"> <li>• “Receive one or more opioid prescriptions totaling” 90 MME or more; OR</li> <li>• When patients is “receiving a prescription that results in concurrent use of an opioid and benzodiazepines.”</li> </ul>
<a href="#">Washington</a>	Nov. 1, 2018; Jan. 2, 2019	Prescribe	There are minor variations in regulations that apply to different prescribing professionals. However, all require the prescriber to “confirm or provide” a prescription for naloxone for each instance of “high dose” prescription and/or “high risk patient.” “High dose” is defined as 90 MED (DO, Osteopathic PA, Podiatry). “High risk” definitions generally include patients at increased risk of morbidity or mortality, such as from comorbidities, polypharmacy, history of substance use disorder or abuse, aberrant behavior, high dose opioid prescription, or the use of any central nervous system depressant. (MD, PA, APRN, DDS)

## Conclusion

Naloxone quickly and effectively reverses opioid overdose. Efforts to increase access to this lifesaving medication are urgently needed. Early evidence suggests that requirements that it be prescribed or offered result in increases in naloxone dispensed from pharmacies, and may be an important tool in increasing the amount of naloxone available for use in an overdose emergency.<sup>15,16</sup> Research may be helpful in determining whether some provisions are more impactful than others, as well as their cost-effectiveness compared to modalities like non-pharmacy community distribution.



## Appendix 1: In-depth Explanation of Naloxone Prescription Mandates

### State: Arizona

Date: Approved by Governor January 26, 2018, effective April 26, 2018

Citation: [Ariz. Rev. Stat. § 32-3248.01](#)

Explanation: Law requires the co-prescribing of naloxone by the “prescribing health professional” when the patient is issued a new prescription for a schedule II opioid that is greater than 90 MME per day.

### State: California

Date: Signed Sept. 8, 2018, effective January 1, 2019, amended Sept. 5, 2019

Citation: [Ca. Bus. & Prof. §§ 740-742](#)

Amended Sept. 5, 2019 as follows:

- Law’s requirements are triggered only when the prescriber is prescribing an opioid or benzodiazepine to a patient (previously the requirements appeared to apply to every prescriber);
- Law modified to require naloxone prescription not only specifically when opioid and benzodiazepine are prescribed concurrently, but in any instance when the opioid is prescribed within a year from when a benzodiazepine has been dispensed;
- Law modified to remove education requirement where patient declines or has received education in previous 24 months;
- Law modified to add exemptions when ordering medication to be administered in the inpatient or outpatient setting or to a patient who is terminally ill.

Explanation: When prescribing an opioid or benzodiazepine medication to a patient, a prescriber is required to offer a prescription for (but not necessarily prescribe) naloxone to a patient under the following circumstances:

- Patient is receiving 90 MME or higher per day; OR
- “An opioid medication is prescribed within a year from the date a prescription for benzodiazepine has been dispensed to the patient”; OR
- Patient is at increased risk of overdose, “including a patient with a history of overdose, a patient with a history of substance use disorder, or a patient at risk for returning to a high dose of opioid medication to which the patient is no longer tolerant.”

Prescriber is also required to provide education “on overdose prevention and the use of naloxone hydrochloride...” to the patient and “one or more persons designated by the patient, or, for a patient who is a minor, to the minor’s parent or guardian,” unless the patient declines the education or has received it within the past 24 months.

Requirement does not apply:

- When the prescriber is a veterinarian;
- When the patient is an inmate or a youth under the jurisdiction of the Department of Corrections and Rehabilitation or the Division of Juvenile Justice within the Department of Corrections and Rehabilitation;
- When ordering medication to be administered in the inpatient or outpatient setting;
- When prescribing to a patient who is terminally ill.

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A prescriber who fails to comply with either the prescription or education requirements “shall be referred to the appropriate licensing board solely for the imposition of administrative sanctions deemed appropriate by that board.”

**State: Florida**

Date: Signed March 19, 2018, Effective July 1, 2018

Citation: [Florida Stat. § 456.44\(6\)](#)

Explanation: Where a schedule II opioid is prescribed for the treatment of pain related to a traumatic injury with an Injury Severity Score of 9 or greater, naloxone must be “concurrently” prescribed.

**State: New Jersey**

Date: May 21, 2020

Citation: [DCA Administrative Order No. 2020-08](#)

Explanation: When “controlled dangerous substances” are prescribed continuously for management of chronic pain, a practitioner of medicine, dentistry, optometry, or advanced practice nursing must provide a prescription for naloxone if patient has a total prescription of 90 MME or more per day or is taking both an opioid and a benzodiazepine. Order expires when the state COVID-19 public health emergency or state of emergency ends, whichever is later, unless expressly revoked or superseded.

The order largely mirrors a proposed rule (N.J.A.C. 13:35-7.6(f)(8)) which is currently in the rulemaking process. That rule would require that a prescriber “Provide a prescription for an opioid antidote if the patient has one or more prescriptions totaling 90 morphine milligram equivalents or more per day, or is concurrently obtaining an opioid and a benzodiazepine, and document within the patient record the action taken.”

**State: New Mexico**

Date: Signed March 28, 2019, effective June 14, 2019

Citation: [N. M. Stat. Ann. § 24-2D-7](#)

Explanation:

- Health care provider who prescribes, distributes, or dispenses an opioid analgesic to a patient for the first time must advise on risks and inform the patient of the availability of opioid antagonist;
- For patients to whom opioid antagonist has previously been prescribed, distributed, or dispensed: must advise and inform the first time that provider prescribes, dispenses, or distributes opioid antagonist each calendar year;
- When prescribing five-day supply or greater of an opioid, must co-prescribe opioid antagonist (naloxone). Must concurrently provide written information regarding effects of opioid antagonist and how to administer it, as well as a warning that the person should call 911 immediately after administering.

**State: Ohio**

Date: Effective December 23, 2018 (physician); December 22, 2018 (APRN)

Citation: [Ohio Admin. Code 4731-11-14](#) (physician); [4723-9-10\(K\)\(2\)](#) (APRN)

Explanation: When treating subacute or chronic pain with an opioid analgesic, physician or advanced practice registered nurse “shall offer” a prescription for naloxone to a patient receiving an opioid analgesic prescription under any of the following circumstances:

- The patient has a history of prior opioid overdose;
- The dosage prescribed exceeds a daily average of eighty MED (Morphine Equivalent Dose);
- The patient is co-prescribed a benzodiazepine, sedative hypnotic drug, carisprodal [*as written, likely intended to be “carisoprodol”*], tramadol, or gabapentin;
- The patient has a concurrent substance use disorder.

When the daily opioid dosage averages fifty MED or greater (for APRNs, only where the dosage exceeds 50 MED) the provider “shall consider offering” a prescription for naloxone.

**State: Rhode Island**

Date: Filed June 13, 2018, Effective July 2, 2018

Citation: [216 R.I. Code R. § 20-20-4.4](#)

Explanation: Prescriber must co-prescribe naloxone when:

- Prescribing an opioid to a patient who is receiving 50 MME or greater – or document in the medical record why co-prescribing is not appropriate for the patient;
- Prescribing any dose of an opioid when a benzodiazepine has been prescribed in the past thirty days, or will be prescribed at the visit. Prescriber also required to note medical necessity of the co-prescription of the opioid and the benzodiazepine and explain why the benefit outweighs the risk;
- Prescribing any dose of an opioid to a patient with a prior history of opioid use disorder or overdose. Prescribers must also note medical necessity of prescribing of the opioid and explain why the benefit outweighs the risk given the patient’s previous history.

**State: Virginia**

Date: Effective March 15, 2017 (as an emergency regulation); August 8, 2018

Citation: [18 Va. Admin. Code § 85-21-40](#) (physicians); § [60-21-103](#) (dentists)

Explanation:

Physicians:

When initiating opioid treatment, “Naloxone shall be prescribed for any patient when risk factors of prior overdose, substance misuse, doses in excess of 120 MME/day, or concomitant benzodiazepine are present.”

Dentists:

Naloxone shall be prescribed for any patient when there is any risk factor of prior overdose, substance abuse, or doses in excess of 120 MME per day and shall be considered when concomitant use of benzodiazepine is present.

**State: Vermont**

Date: Effective July 1, 2017; amended March 1, 2019

Citation: [Vt. Admin. Code 12-5-53:7.0](#)

Explanation: Prescribers required to co-prescribe naloxone or document in the medical record that a patient has a valid prescription for or is in possession of naloxone for all patients “who receive one or more opioid prescriptions totaling a Morphine Milligram Equivalent Daily Dose of 90 or more” as well as those “receiving a prescription that results in concurrent use of an opioid and benzodiazepines.”

Amendments modified previous requirement that prescriber prescribe naloxone to all patients receiving 90 MME or greater and all patients receiving an opioid “if there is a concurrent prescription for benzodiazepines.” Amendments also clarify that in the event there are multiple prescribers, the one responsible for the naloxone prescription is the one whose prescription triggered the provisions of the regulation.

**State: Washington**

Date: Effective Nov. 1, 2018 (ARNP, DO, OPA, podiatrists); Jan. 1, 2019 (MD, PA); Jan. 26, 2019 (DDS)

Citation: Various, [collected here](#).

Explanation: Minor variations, but all required to “confirm or provide” prescription for naloxone for “high risk patients” or “when high dose opioids are prescribed.” For Advanced Registered Nurse Practitioners, the requirements are triggered at or above 50 MED for non high-risk patients.



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## References

- <sup>1</sup> N. Wilson, et al., *Drug and Opioid-Involved Overdose Deaths - United States, 2017-2018*, 69 MMWR MORB MORTAL WKLY REP (2020).
- <sup>2</sup> *Id.*
- <sup>3</sup> See J. M. Chamberlain & B. L. Klein, *A comprehensive review of naloxone for the emergency physician*, 12 AM J EMERG MED (1994).
- <sup>4</sup> E. Wheeler & Doe-Simkins M., *Harm Reduction programs distribute one million doses of naloxone in 2019*, MEDIUM, 2020, <https://medium.com/@ejwharmreduction/harm-reduction-programs-distribute-one-million-doses-of-naloxone-in-2019-4884d3535256>.
- <sup>5</sup> B. H. Lambdin, et al., *Identifying gaps in the implementation of naloxone programs for laypersons in the United States*, 52 INT J DRUG POLICY (2018).
- <sup>6</sup> N. Wilson, et al., *Drug and Opioid-Involved Overdose Deaths - United States, 2017-2018*, 69 MMWR MORB MORTAL WKLY REP (2020).
- <sup>7</sup> D. Dowell, et al., *CDC Guideline for Prescribing Opioids for Chronic Pain - United States, 2016*, 65 MMWR RECOMM REP (2016).
- <sup>8</sup> DEPT OF HEALTH AND HUMAN SERVICES, NALOXONE: THE OPIOID REVERSAL DRUG THAT SAVES LIVES, *available at* <https://www.hhs.gov/opioids/sites/default/files/2018-12/naloxone-coprescribing-guidance.pdf>.
- <sup>9</sup> Food and Drug Administration, *FDA Requiring Labeling Changes for Opioid Pain Medicines, Opioid Use Disorder Medicines Regarding Naloxone*(2020), *available at* <https://www.fda.gov/news-events/press-announcements/fda-requiring-labeling-changes-opioid-pain-medicines-opioid-use-disorder-medicines-regarding>.
- <sup>10</sup> C. S. Davis & D. Carr, *Over the counter naloxone needed to save lives in the United States*, 130 PREV MED (2020).
- <sup>11</sup> R. L. Haffajee, et al., *Legal requirements and recommendations to prescribe naloxone*, 209 DRUG ALCOHOL DEPEND (2020).
- <sup>12</sup> It is therefore incorrect to refer to these laws collectively as “co-prescribing” mandates. California initially appeared to require that naloxone be offered even where the provider was not themselves prescribing an opioid or benzodiazepine, but was amended September 5, 2019 to apply only to the prescriber of those medications. See Ca. Bus. & Prof. §§ 740-742.
- <sup>13</sup> Ca. Bus. & Prof. § 742.
- <sup>14</sup> In some states the naloxone mandate is within the code section that regulates opioid prescribing. In some cases, violation of the provisions of that section is set out in the law. For example, Rhode Island law specifies that a person who violates the section of the law that contains the naloxone prescribing requirement “shall be subject to the penalty provisions as specified in the [Uniform Controlled Substances Act].” 216 R.I. Code R. § 20-20-4.4.8. It is not clear which penalty is intended. The Uniform Controlled Substances Act contains a “General Penalty Clause,” which specifies that “Any person who violates any provision of this chapter, the penalty for which is not specified in this chapter, and of the rules and regulations of the director of health made under authority of this chapter, shall be sentenced to a term of imprisonment of not more than one year, a fine of five hundred dollars (\$500), or both.” R.I. Gen. Laws § 21-28-4.09.



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Ohio law specifies that failure to follow requirements in the section in which the requirement is listed is a violation of one or more provisions subject to discipline by the state medical board. It is presumed that, in most states, failure to comply with the mandate would be a matter for the licensing board that regulates the relevant provider. Ohio Admin. Code 4731-11-02(E).

<sup>15</sup> T. C. Green, et al., *Laws Mandating Coprescription of Naloxone and Their Impact on Naloxone Prescription in Five US States, 2014-2018*, 110 AM J PUBLIC HEALTH (2020).

<sup>16</sup> M. Sohn, et al., *Association of Naloxone Coprescription Laws With Naloxone Prescription Dispensing in the United States*, 2 JAMA NETW OPEN (2019).