



HARM REDUCTION AND OVERDOSE PREVENTION Fact Sheet

Naloxone Prescription Mandates

Background

The United States continues to experience a crisis of preventable overdose death and disability. Over 107,000 people died of a drug overdose in 2021, the highest number on record.¹ Opioids were involved in approximately 80% of these deaths.² 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.³ Nearly every person who died of a witnessed opioid overdose could have been saved if those present had naloxone with them.

It is estimated that, of the approximately 17 million doses of naloxone distributed in the US in 2021, 2.6 million were distributed from community pharmacies.⁴ For comparison, the non-profit naloxone distributor Remedy Alliance distributed over one million doses of naloxone to harm reduction organizations for further distribution in its first ten months of operation in 2022.⁵ While the distribution of naloxone by harm reduction organizations should be a top priority for increasing access to the medication, pharmacies are an important source and potentially underutilized source of naloxone.

The proportion of opioid-related overdoses attributable to pharmacy-obtained opioids has fallen with the decrease in prescription of those opioids, but they still account for many opioid-related fatalities.⁶ It is therefore reasonable to supplement community naloxone distribution with pharmacy-based naloxone access, particularly for 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,⁷ and the Food and Drug Administration requires that the labels of opioid medications recommend that prescribers discuss naloxone with patients when prescribing those medications.⁸

To increase access to this lifesaving medication, many states have passed laws that require that naloxone be prescribed or offered to some patients.⁹ This fact sheet illustrates the progression of those laws over time, describes the requirements in place as of January 1, 2023, and provides links to the text of the relevant laws.



Naloxone prescribing or dispensing mandates

The first legal requirements to prescribe or dispense naloxone became effective in 2017.¹⁰ As of January 1, 2023, eighteen states have enacted laws that require some medical professionals to prescribe, offer a prescription for, or dispense naloxone to some individuals under their care.¹¹ Eleven states (AZ, AR, FL, IN, NJ, NM, NY, RI, VT, VA, WA) require one or more medical professionals to prescribe naloxone under certain circumstances,¹² while seven states (CA, CO, IL¹³, KY, OH, SC, TN) only require that a prescriber, pharmacist, or physician *offer* naloxone.¹⁴ There does not appear to be a clear geographic or temporal trend in adoption of these laws, although newer laws are both more likely to include clear penalties for non-compliance and to apply to medical professionals other than those that issue a prescription for opioids.

The circumstances that trigger these requirements vary widely. While most states require that naloxone be prescribed or offered when opioids over a certain Morphine Milligram Equivalent (MME) per day 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. Indiana's law only applies when buprenorphine treatment is being initiated. Where an MME requirement is present, the triggering level ranges from 50 (AR, RI, SC) to 120 (VA). 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. In all states but Washington and South Carolina, the requirements are triggered only when the provider is prescribing or dispensing an opioid.¹⁵

None of these laws provide clear penalties for non-compliance. Only four state laws (AR, CA, SC, TN) discuss penalties specific to failing to follow the prescribing mandate, which are largely left to the discretion of the appropriate licensing board.¹⁶ In some states the naloxone mandate is within the code section that regulates opioid prescribing and, in some cases, violation of the provisions of that section is set out in the law¹⁷ or is explicitly described as a matter for the licensing board that regulates the relevant provider, as is the case in Florida, New Jersey and Ohio.¹⁸

Table 1: Year naloxone mandate enacted			
Year	# of states	States	
2017	2	VA, VT	
2018	5	AZ, FL, OH, RI, WA	
2019	3	CA, IN, NM	
2020	1	NJ	
2021	4	AR, CO, KY, SC	
2022	2	NY, TN	

Table 1 lists the states that enacted a relevant law, and the year in which the mandate was enacted. Figure 1 shows the number of relevant laws that became effective in each year from 2017 to 2022.¹⁹ Table 2 provides an overview of the requirements imposed by each law, including the circumstances in which it applies and the professionals to which it applies. Appendix 1 provides a more detailed explanation of these laws, including the date 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 between physician and non-physician prescribers.

Conclusion

Naloxone quickly and effectively reverses opioid overdose. A "yes/and" approach to increase access to this lifesaving medication, so that it is always immediately available at an opioid overdose, is urgently needed. Early evidence suggests that requirements that naloxone 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.²⁰ Research may be helpful in determining whether some provisions of these laws are more impactful than others, as well as their cost-effectiveness compared to modalities like non-pharmacy community distribution.



State	Effective date	Requirement	Brief explanation
Arizona	April 26, 2018	Health professional must prescribe	 Law requires the co-prescribing of naloxone by a prescribing "health professional" when: The patient is issued a new prescription for a schedule II opioid that is greater than 90 MME per day; AND The prescription is to be filled or dispensed outside of a health care institution.
Arkansas	July 28, 2021	Healthcare professional must prescribe	 Law requires the co-prescribing of naloxone by a "healthcare professional" to a patient in any of the following circumstances, unless they don't believe it's in the best interest of the patient: The opioid dosage prescribed or dispensed is greater than or equal to 50 MME per day; OR A benzodiazepine has been "prescribed or dispensed for the patient in the past" or will be prescribed or dispensed at the same time as the opioid; OR The patient has a history of opioid use disorder or drug overdose. This requirement does not apply to a patient receiving hospice or other end-of-life care or those who have an "existing prescription" for naloxone.
California	January 1, 2019	Prescriber must offer	 Law requires prescribers to offer a prescription for (but not necessarily prescribe) naloxone to a patient who is being prescribed an opioid or benzodiazepine and: Receiving 90 MME or higher per day; OR Receiving any opioid prescription within a year of filling benzodiazepine prescription; OR 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." This requirement does not apply when: the patient is an inmate or a youth under

Table 2: Overview of laws that mandate naloxone prescribing

			 the jurisdiction of the Department of Corrections and Rehabilitation or the Division of Juvenile Justice within the Department of Corrections and Rehabilitation; OR ordering medication to be administered in the inpatient or outpatient setting; OR prescribing to a patient who is terminally ill.
Colorado	September 7, 2021	Pharmacist must offer	 Law requires a pharmacist who dispenses a prescription opioid to offer to dispense naloxone to the individual to whom the opioid is being dispensed at least once a year, in either of the following circumstances: The individual is, at the same time, prescribed a benzodiazepine, a sedative hypnotic drug, carisoprodol, tramadol, or gabapentin; OR The opioid prescription is at or in excess of 90 MME. The mandate does not apply to patients in hospice or palliative care or residents in a veterans community living center.
<u>Florida</u>	July 1, 2018	Prescriber must prescribe	Law requires naloxone to be prescribed when a Schedule II controlled substance is prescribed for the treatment of pain related to a traumatic injury with an Injury Severity Score of 9 or greater.
<u>Illinois</u>	January 1, 2023	Pharmacist must offer	Law requires a pharmacist, before dispensing an opioid, to inform patients that opioids are addictive and to offer to dispense naloxone.
<u>Indiana</u>	July 1, 2019	Health care provider must prescribe	 Law requires a "health care provider that prescribes for a patient in an office based opioid treatment setting" to prescribe naloxone and provide education on how to fill the prescription when buprenorphine is initiated. This requirement does not apply in the following settings: An adult or juvenile correctional facility operated by the state or a local unit; OR A hospital licensed under IC 16-21-2; OR A facility that is certified by the division; OR An opioid treatment program that has been certified or licensed by the division under IC 12-23-18; OR A health facility licensed under IC 16-28; OR The Indiana Veterans' Home.

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<u>Kentucky</u>	June 29, 2021	Pharmacist must offer	Law requires that a pharmacy that sells hypodermic syringes or needles make available a verbal, physical, or electronic offer to provide a prescription for naloxone. This requirement does not apply to the sale of hypodermic syringes or needles dispensed as a prescription or in conjunction with a prescription medication that requires reconstitution or administration with a syringe.
New Jersey	May 21, 2020 ²¹	Practitioner must prescribe	 One law requires a healthcare practitioner who has issued a patient a prescription for an "opioid drug" to co-prescribe naloxone if: The patient has a history of substance use disorder; OR The prescription for the opioid drug is for a daily dose of more than 90 MME; OR The patient holds a current prescription for a Schedule III or Schedule IV benzodiazepine. A second law requires that, "[w]hen controlled dangerous substances are continuously prescribed for management of chronic pain," a practitioner is required to: Advise the patient, or the patient's parent or guardian if the patient is under 18 years of age and is not an emancipated minor, of the availability of naloxone; AND Provide a prescription for naloxone if the patient has one or more prescriptions totaling 90 MME or more per day, or is concurrently obtaining an opioid and a benzodiazepine. Under either law, the requirements do not apply to a prescription for a patient in the following circumstances: The patient is currently in active treatment for cancer; OR The patient is a resident of a long term care facility; OR The patient is a resident of a long term care facility; OR The patient is not required to issue more than one prescription for an opioid and prescribed are for use in the treatment of substance use disorder or opioid dependence.

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<u>New Mexico</u>	June 14, 2019	Health care provider must prescribe	Health care provider who prescribes, distributes, or dispenses an opioid analgesic to a patient for the first time must advise the patient on risks of overdose and inform the patient of the availability of naloxone. Additionally, provider must prescribe naloxone when prescribing a five-day or greater supply of opioid analgesics.
<u>New York</u>	June 27, 2022	Prescriber must prescribe	 Law requires a prescriber to prescribe naloxone the first time they prescribe an opioid to a patient each year for use in a setting other than a general hospital or nursing home, or to a patient receiving hospice care, if any of the following risk factors are present: A history of substance use disorder; OR High dose or cumulative prescriptions that result in 90 MME or higher per day; OR Concurrent use of opioids and benzodiazepine or nonbenzodiazepine sedative hypnotics.
Ohio	December 23, 2018	Physician must offer	 When treating subacute or chronic pain, a physician is required to offer a prescription for naloxone to a patient receiving an opioid analgesic prescription in any of the following circumstances: The patient has a history of prior opioid overdose; OR The dosage prescribed exceeds a daily average of 80 MED (Morphine Equivalent Dose), or at lower doses if the patient is coprescribed a benzodiazepine, sedative hypnotic drug, carisprodol [as written, likely intended to be "carisoprodol"], tramadol, or gabapentin; OR The patient has a concurrent substance use disorder. These requirements do not apply when an opioid analgesic is prescribed to a patient in hospice care, a patient who has terminal cancer or another terminal condition, or an inpatient prescription. Similar rules apply to Advanced Practice Registered Nurses. See Appendix for details.

Rhode Island	July 2, 2018	Prescriber must prescribe	 Prescriber must co-prescribe naloxone when: Prescribing an opioid to a patient who is receiving 50 MME or greater in aggregate, or document in the medical record why co-prescribing is not appropriate for the patient; OR Prescribing any dose of an opioid when a benzodiazepine has been prescribed in the past 30 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 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 point 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.
South Carolina	July 25, 2021	Prescriber must offer	 Law requires a prescriber to offer a prescription for naloxone to a patient in any of the following circumstances: The prescription dosage for the patient is greater than or equal to 50 MME of an opioid medication per day; OR An opioid medication is prescribed concurrently with a prescription for benzodiazepine; OR The patient presents with an increased risk for overdose, including 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.
<u>Tennessee</u>	July 1, 2022	Healthcare prescriber must offer	 Law requires a healthcare prescriber, when prescribing more than a three-day supply of an opioid medication, to offer a prescription for naloxone if: The healthcare provider prescribes an opioid medication concurrently with a prescription for a benzodiazepine; OR The patient presents with an increased risk for overdose, including a history of overdose, a history of substance use disorder, or being at risk for returning to a high dose of opioid medication to which the patient is no longer tolerant. This requirement does not apply to an opioid prescription written as part of a patient's palliative care treatment, and it does not apply to prescriptions written by licensed veterinarians.

<u>Vermont</u>	July 1, 2017	Prescriber must prescribe	 Law requires prescribers to co-prescribe naloxone or document in the medical record that a patient has a valid prescription for naloxone (or states they are in possession of naloxone) in the following circumstances: The patient receives one or more opioid prescriptions totaling a daily dose of 90 MME or more; OR The patient receives a prescription that results in concurrent use of an opioid and benzodiazepines. 2019 update: Where there is more than one prescriber involved in a patient's care, the prescriber responsible for the naloxone prescription is the one whose prescription triggered the provisions of the regulation.
<u>Virginia</u>	March 15, 2017	Prescriber must prescribe	 When initiating opioid treatment, physicians, podiatrists, and physician assistants are required to prescribe naloxone for any patient "when risk factors of prior overdose, substance misuse, doses in excess of 120 MME/day, or concomitant benzodiazepine are present." This requirement does not apply to any of the following: The treatment of acute or chronic pain related to cancer or sickle cell; OR A patient in hospice care; OR A patient in palliative care; OR The treatment of acute or chronic pain during an inpatient hospital admission or in a nursing home or an assisted living facility that uses a sole source pharmacy; OR A patient enrolled in a clinical trial as authorized by state or federal law.
<u>Washington</u>	November 1, 2018	Prescriber must 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." See additional details in Appendix.





Appendix 1: In-depth explanation of naloxone prescription mandates

Arizona

Date: Approved January 26, 2018; effective April 26, 2018 Citation: Ariz. Rev. Stat. § 32-3248.01(D)

Explanation: Law requires the co-prescribing of "naloxone hydrochloride or any other opioid antagonist that is approved by the United States food and drug administration to treat opioid-related overdoses" 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 and that is to be filled or dispensed for a patient outside of a health care institution.

Arkansas

Date: Approved April 12, 2021; effective July 28, 2021 Citation: Ark. Code Ann. § 20-13-1805(b)(1)

Explanation: Law requires the co-prescribing of naloxone or other opioid antagonist by a "healthcare professional" to a patient if the patient does not have an existing prescription for an opioid antagonist and one of the following conditions is met:

- The opioid dosage prescribed or dispensed is greater than or equal to 50 MME per day; OR
- A benzodiazepine has been prescribed or dispensed for the patient in the past or will be prescribed or dispensed at the same time as the opioid; OR
- The patient has a history of opioid use disorder or drug overdose.

This requirement does not apply to a patient receiving hospice or other end-of-life care.

If the healthcare professional does not believe that it is in the best interest of a patient to co-prescribe an opioid antagonist, the healthcare professional "shall make documentation to that effect as provided in the guidance or rules of the appropriate licensing entity" (and presumably may choose not to co-prescribe naloxone). A healthcare professional who co-prescribes as required by the law must also "provide counseling and patient education to a patient, or a patient's parent or guardian if the patient is less than eighteen (18) years of age, as provided in the guidance or rules of the appropriate licensing entity." A healthcare professional who fails to co-prescribe an opioid antagonist as required by the law "may be referred to the appropriate licensing board for administrative sanctions or disciplinary action."

Pursuant to <u>Ark. Code Ann. § 20-13-1805(e)(1)</u>, the Arkansas State Board of Pharmacy has published <u>opioid</u> <u>co-prescribing guidance</u>.

California

Date: Signed September 8, 2018; effective January 1, 2019; amended September 5, 2019 Citation: <u>Ca. Bus. & Prof. §§ 740-742</u>

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 in 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.

This requirement does not apply in the following situations:

- When the prescriber is a veterinarian; OR
- 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; OR
- When ordering medication to be administered in the inpatient or outpatient setting; OR
- When prescribing to a patient who is terminally ill.

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."

Amended September 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 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 decline 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 in addition to existing exemptions applicable to correctional settings.

Colorado

Date: Approved June 4, 2021; effective September 7, 2021

Citation: Colo. Rev. Stat. Ann. § 12-280-123(1)(c)

Explanation: Law requires a pharmacist who dispenses a prescription order "for a prescription drug that is an opioid" to inform the individual of the potential dangers of a high dose of an opioid, and "offer to dispense to the individual to whom the opioid is being dispensed, on at least an annual basis, an opiate antagonist approved by the FDA for the reversal of an opioid overdose" in either of the following circumstances:

- The individual is, at the same time, prescribed a benzodiazepine, a sedative hypnotic drug, carisoprodol, tramadol, or gabapentin; OR
- The opioid prescription is at or in excess of 90 MME, as described in the guidelines of the federal centers for disease control and prevention.

This requirement does not apply to a patient who is in hospice or palliative care or a resident in a veterans community living center.

If the individual accepts the opioid antagonist, the pharmacist is required to counsel them on how to use it in the event of an overdose and notify them of available generic and brand-name opiate antagonists.

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, an "emergency opioid antagonist" must be "concurrently" prescribed.

Enforcement is potentially provided by <u>Florida Stat. § 456.072(mm</u>), which lists "Failure to comply with controlled substance prescribing requirements of s. 456.44" as an act that constitutes ground for which specified disciplinary actions may be taken. Potential penalties range from issuance of a letter of concern to license revocation and the imposition of a \$10,000 fine per offense.



Illinois

Date: Approved June 2, 2022; effective January 1, 2023

Citation: <u>225 III. Comp. Stat. Ann. 85/19.1(c)</u> (amended by <u>2022 III. Legis. Serv. P.A. 102-1040 (S.B. 2535)</u>); <u>720 III. Comp. Stat. Ann. 570/312(a-10)</u> (amended by <u>2022 III. Legis. Serv. P.A. 102-1040 (S.B. 2535)</u>) Explanation: Law requires a pharmacist, before dispensing an opioid, to inform patients that opioids are addictive and to offer to dispense an opioid antagonist.

Indiana

Date: Approved May 5, 2019; effective July 1, 2019 Citation: Ind. Code Ann. § 12-23-20-2(b)(11)

Explanation: Law requires a physician who is providing office-based opioid treatment to prescribe an "overdose intervention drug" and provide education on how to fill the prescription when buprenorphine is initiated.

This requirement does not apply in the following settings:

- An adult or juvenile correctional facility operated by the state or a local unit; OR
- A hospital licensed under IC 16-21-2; OR
- A facility that is certified by the division; OR
- An opioid treatment program that has been certified or licensed by the division under IC 12-23-18; OR
- A state institution; OR
- A health facility licensed under IC 16-28; OR
- The Indiana Veterans' Home.

Kentucky

Date: Approved March 22, 2021; effective June 29, 2021; amended July 14, 2022 Citation: <u>Ky. Rev. Stat. Ann. § 217.177(2)</u>

Explanation: Law requires that a pharmacy selling hypodermic syringes or needles must make available a verbal, physical, or electronic offer to provide a prescription for an opioid antagonist as that term is defined in the state naloxone access law. Prior to the 2022 amendment, the requirement was for a "naloxone" prescription.

This requirement does not apply to the sale of hypodermic syringes or needles dispensed as a prescription or in conjunction with a prescription medication that requires reconstitution or administration with a syringe.

New Jersey

Date: Previous requirement effective May 21, 2020; current law effective January 19, 2021 (co-prescribing with "controlled dangerous substances"); April 19, 2021 (co-prescribing with an "opioid drug") Citation: N.J. Stat. Ann. § 24:21-15.2(j); N.J. Admin. Code § 13:35-7.6(j)

Explanation: Law requires a healthcare practitioner who has issued a patient a prescription for an "opioid drug" to co-prescribe an "opioid antidote" in any of the following circumstances:

- The patient has a history of substance use disorder; OR
- The prescription for the opioid drug is for a daily dose of more than 90 MME; OR
- The patient holds a current, valid prescription for a benzodiazepine drug that is a Schedule III or Schedule IV controlled dangerous substance.

The law specifies that a practitioner is not required to issue more than one prescription for an opioid antidote to such a patient per year.

"When controlled dangerous substances are continuously prescribed for management of chronic pain," a practitioner is required to take the following actions:

 Advise the patient, or the patient's parent or guardian if the patient is under 18 years of age and is not an emancipated minor, of the availability of an opioid antidote; AND • 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.

These requirements do not apply to a prescription for a patient in the following circumstances:

- The patient is currently in active treatment for cancer; OR
- The patient is receiving hospice care from a licensed hospice or palliative care; OR
- The patient is a resident of a long term care facility; OR
- The medications that are being prescribed are for use in the treatment of substance use disorder or opioid dependence.

Violation of the co-prescribing with a "controlled substance" section of the law may be enforced by N.J. Admin. Code § 13:35-7.10 which deems a violation as potential grounds to suspend, deny or revoke a certificate registration or license by the appropriate board.

A previous administrative order, <u>DCA Administrative Order No. 2020-08</u> (effective May 21, 2020), required that 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 to a patient who has a total prescription of 90 MME or more per day or is taking both an opioid and a benzodiazepine. That order was set to expire when the state COVID-19 public health emergency or state of emergency ended, whichever was later, unless expressly revoked or superseded.

New Mexico

Date: Signed March 28, 2019; effective June 14, 2019 Citation: N. M. Stat. Ann. § 24-2D-7

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

Under <u>N.M. Stat. Ann. § 24-23-3</u>, as agency funding and agency supplies of naloxone permit, an opioid treatment center agency operating a federally certified program to dispense methadone or other narcotic replacement as part of a detoxification treatment or maintenance treatment is required to provide each patient it treats with the following:

- An opioid overdose education that (1) conforms to department of health or federal substance abuse and mental health services administration guidelines for opioid overdose education; (2) explains the causes of an opioid overdose; (3) instructs when and how to administer in accordance with medical best practices; and (4) explains how to contact appropriate emergency medical services; AND
- Two doses of naloxone in either a generic form or in a form approved by the federal food and drug administration; AND
- A prescription for naloxone.

Under <u>N.M. Stat. Ann. § 33-2-51</u>, as corrections department funding and department supplies of naloxone permit, upon discharge of an inmate who has been diagnosed with an opioid use disorder from a corrections facility, regardless of whether that inmate has received treatment for that disorder, the corrections department is required to take the following actions:

• Ensure that the inmate is provided with opioid overdose education that (1) conforms to department of health or federal substance abuse and mental health services administration guidelines for opioid overdose education; (2) explains the causes of an opioid overdose; (3) instructs when and how to administer in accordance with medical best practices; and (4) explains how to contact appropriate

emergency medical services; AND

• Provide the inmate, as the inmate leaves the correctional facility, with (1) two doses of naloxone in either a generic form or in a form approved by the federal food and drug administration; and (2) a prescription for naloxone.

New York

Date: Signed December 30, 2021; effective June 27, 2022 Citation: N.Y. Pub. Health Law § 3309(7)

Explanation: Law requires a prescriber to prescribe an opioid antagonist with the first prescription to a particular patient of an opioid of each year for use in a setting other than a general hospital or nursing home, or when a practitioner is prescribing a controlled substance to a patient under the care of hospice, if any of the following risk factors are present:

- A history of substance use disorder; OR
- High dose or cumulative prescriptions that result in 90 MME or higher per day; OR
- Concurrent use of opioids and benzodiazepine or nonbenzodiazepine sedative hypnotics.

Ohio

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

Citation: Ohio Admin. Code 4731-11-14(B)(7) (physician); 4723-9-10(J)(2)(b) (APRN)

Explanation: When treating subacute or chronic pain with an opioid analgesic, a physician is required to offer a prescription for naloxone to a patient receiving an opioid analgesic prescription in any of the following circumstances:

- The patient has a history of prior opioid overdose; OR
- The dosage prescribed exceeds a daily average of 80 MED (Morphine Equivalent Dose), or at lower doses if the patient is co-prescribed a benzodiazepine, sedative hypnotic drug, carisprodol [as written, likely intended to be "carisoprodol"], tramadol, or gabapentin; OR
- The patient has a concurrent substance use disorder.

Before prescribing an opioid analgesic for sub-acute or chronic pain, an APRN is required to offer the patient a prescription for naloxone in the following circumstances:

- The patient has a prior history of opioid overdose; OR
- The patient is co-prescribed a benzodiazepine, sedative hypnotic drug, carisprodal, tramadol, or gabapentin; OR
- The patient has a concurrent substance use disorder; OR
- The dosage exceeds 80 MED.

In addition, when the daily opioid dosage averages 50 MED or greater (for APRNs, only where the dosage exceeds 50 MED), the provider "shall consider offering" a prescription for naloxone.

These requirements do not apply when an opioid analgesic is prescribed to a patient in hospice care, a patient who has terminal cancer or another terminal condition, or an inpatient prescription.

Rhode Island

Date: Filed June 13, 2018; effective July 2, 2018; amended January 2, 2020 Citation: <u>216 R.I. Code R. § 20-20-4.4(M)</u>

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; OR
- Prescribing any dose of an opioid when a benzodiazepine has been prescribed in the past 30 days, or will be prescribed at the visit. Prescriber also required to note medical necessity of the coprescription of the opioid and the benzodiazepine and explain why the benefit outweighs the risk; OR
- 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.

The January 2, 2020 change was not substantive.

Violation of the co-prescribing section of the law may subject the prescriber to possible imprisonment up to a year, a five hundred dollar fine, or both. (216 R.I. Code R. § 20-20-4.4.8; R.I. Code R. § 21-28-4.09.)

South Carolina

Date: Approved April 26, 2021; effective July 25, 2021 Citation: <u>S.C. Code Ann. § 44-53-361</u>

Explanation: Law requires a prescriber to offer a prescription for naloxone hydrochloride or another drug approved by the United States Food and Drug Administration for the complete or partial reversal of opioid depression to a patient in any of the following circumstances:

- The prescription dosage for the patient is greater than or equal to 50 MME of an opioid medication per day; OR
- An opioid medication is prescribed concurrently with a prescription for benzodiazepine; OR
- The patient presents with an increased risk for 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.

The prescriber is also required, "consistent with the existing standard of care," to provide education to the patient who receives the naloxone prescription on overdose prevention and the use of the medication and to one or more people designated by the patient or, in the case of a minor, to the minor's parent or guardian.

A prescriber who fails to offer a prescription or provide education in accordance with the statute may be subject to discipline by the appropriate licensing board.

Tennessee

Date: Approved May 25, 2022; effective July 1, 2022

Citation: <u>Tenn. Code Ann. § 53-11-308(i)(1)</u> (co-prescription requirement); <u>§ 53-11-401(b)(1)</u> (penalties for failure to comply with co-prescription requirement)

Explanation: Law requires a healthcare prescriber, when prescribing more than a three-day supply of an opioid medication to a patient, to offer a prescription for an opioid antagonist, or another drug approved by the United States food and drug administration for the complete or partial reversal of an opioid overdose event, if either of the following conditions are met:

- The healthcare provider prescribes an opioid medication concurrently with a prescription for a benzodiazepine; OR
- The patient presents with an increased risk for overdose, including a history of overdose, a history of substance use disorder, or being at risk for returning to a high dose of opioid medication to which the patient is no longer tolerant.

This requirement does not apply to an opioid prescription written as part of a patient's palliative care treatment, and it does not apply to veterinarians. A healthcare provider's failure to comply with these co-prescribing requirements is punishable by a civil penalty assessed by the provider's licensing board, but only if the provider's actions involve a pattern of willful failure to comply.

Vermont

Date: Effective July 1, 2017 (as an emergency regulation); amended March 1, 2019 Citation: <u>Vt. Admin. Code 12-5-53:7.0</u>

Explanation: Law requires prescribers to co-prescribe naloxone or document in the medical record that a patient has a valid prescription for naloxone (or states they are in possession of naloxone) in the following circumstances:

- The patient receives one or more opioid prescriptions totaling a daily dose of 90 MME or more; OR
- The patient receives a prescription that results in concurrent use of an opioid and benzodiazepines.

Where there is more than one prescriber involved in a patient's care, the prescriber responsible for the naloxone prescription is the one whose prescription triggered the provisions of the regulation.

Virginia

Date: Effective March 15, 2017 (as an emergency regulation); August 8, 2018 Citation: <u>18 Va. Admin. Code § 85-21-40(B)(3), § 85-21-70(b)(3)</u> (physicians, podiatrists, physician assistants); <u>§ 60-21-103(A)(4)</u>, <u>§ 60-21-105(2)</u> (dentists)

Explanation: When initiating opioid treatment, physicians, podiatrists, and physician assistants are required to prescribe naloxone for any patient "when risk factors of prior overdose, substance misuse, doses in excess of 120 MME/day, or concomitant benzodiazepine are present."

Note that, under <u>18 Va. Admin. Code § 85-21-10</u>, this requirement does not apply to any of the following:

- The treatment of acute or chronic pain related to cancer or sickle cell; OR
- A patient in hospice care; OR
- A patient in palliative care; OR
- The treatment of acute or chronic pain during an inpatient hospital admission or in a nursing home or an assisted living facility that uses a sole source pharmacy; OR
- A patient enrolled in a clinical trial as authorized by state or federal law.

When initiating opioid treatment for patients with acute pain, dentists are required to prescribe naloxone if "there is any risk factor of prior overdose, substance abuse, or doses in excess of 120 MME per day." Prescribing naloxone "shall be considered" by dentists when there is concomitant use of benzodiazepine.

Washington

Date: Effective November 1, 2018 (ARNP, DO, podiatrists); January 1, 2019 (MD); January 26, 2019 (DDS); January 1, 2022 (emergency departments, behavioral health agencies) Citation: Various, <u>collected here</u>. Explanation:

Advanced Registered Nurse Practitioners

ARNPs must "confirm or provide a current prescription for naloxone when fifty milligrams MED or above, or when prescribed to a high-risk patient." <u>Wash. Admin. Code § 246-840-4980</u>. "High-risk" means "a category of patient 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." <u>Wash. Admin. Code § 246-840-465(8)</u>. "High dose" means ninety milligram morphine equivalent dose (MED), or more, per day. <u>Wash. Admin. Code § 246-840-465(7)</u>. However, presumably, the lower 50 MME limit applies.

Osteopathic physicians

Osteopathic physicians "shall confirm or provide a current prescription for naloxone when high dose opioids are prescribed." <u>Wash. Admin. Code § 246-853-785</u>. "High-dose" means "ninety milligrams MED, or more, per day." <u>Wash. Admin. Code § 246-853-662(6)</u>.

Podiatrists

Podiatrists are required to "confirm or provide a current prescription for naloxone when high-dose opioids are prescribed to a high-risk patient." <u>Wash. Admin. Code § 246-922-785</u>. "High dose" means "ninety milligrams morphine equivalent dose, or more, per day." <u>Wash. Admin. Code § 246-922-662(8)</u>.

Allopathic physicians

Allopathic physicians are required to "confirm or provide a current prescription for naloxone when opioids are prescribed to a high-risk patient." <u>Wash. Admin. Code § 246-919-980</u>. High-risk is defined as "a category of patient at high risk of opioid-induced morbidity or mortality, based on factors and combinations of factors such as medical and behavioral comorbidities, polypharmacy, current substance use disorder or abuse, aberrant behavior, dose of opioids, or the use of any concurrent central nervous system depressant." <u>Wash. Admin. Code § 246-919-852(10)</u>.

Dentists

Dentists are required to "confirm or provide a current prescription for naloxone or refer the patient to a pharmacist for further counseling and evaluation when opioids are prescribed to a high-risk patient." <u>Wash.</u> <u>Admin. Code § 246-817-977</u>. "High-risk" is "a category of patient 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." <u>Wash. Admin. Code § 246-817-906(7)</u>. "High dose" means ninety milligram MED or more, per day. <u>Wash. Admin. Code § 246-817-906(6)</u>.

Emergency departments

A hospital is required to provide a person who presents to an emergency department with symptoms of an opioid overdose, opioid use disorder, or other adverse event related to opioid use with opioid overdose reversal medication upon discharge, unless the treating practitioner determines in their clinical and professional judgment that dispensing or distributing opioid overdose reversal medication is not appropriate or the practitioner has confirmed that the patient already has opioid overdose reversal medication. If the hospital dispenses or distributes opioid overdose reversal medication it must provide directions for use. A person who is provided opioid overdose reversal medication under this section must be provided information and resources about medication for opioid use disorder and harm reduction strategies and services which may be available, such as substance use disorder treatment services and substance use disorder peer counselors. This information should be available in all languages relevant to the communities that the hospital serves. <u>Wash. Rev. Code § 70.41.485</u>.

Behavioral health agencies

For any client presenting with symptoms of an opioid use disorder, or who reports recent use of opioids outside legal authority, all licensed or certified behavioral health agencies that provide individuals treatment for mental health or substance use disorder, withdrawal management, secure withdrawal management, evaluation and treatment, or opioid treatment programs must during the client's intake, discharge, or treatment plan review, as appropriate, take the following actions:

- Prescribe the client opioid overdose reversal medication or utilize the statewide naloxone standing order; AND
 - Assist the client in directly obtaining opioid overdose reversal medication as soon as practical by:
 - Directly dispensing the opioid overdose reversal medication, if authorized by state law; OR
 - Partnering with a pharmacy to obtain the opioid overdose reversal medication on the client's behalf and distributing the opioid overdose reversal medication to the client; OR
 - Assisting the client in utilizing a mail order pharmacy or pharmacy that mails prescription drugs directly to the behavioral health agency or client and distributing the opioid overdose reversal medication to the client, if necessary; OR
 - Obtaining and distributing opioid overdose reversal medication through the bulk purchasing and distribution program established in RCW 70.14.170; OR
 - Using any other resources or means authorized by state law to provide opioid overdose reversal medication.

A person who is provided opioid overdose reversal medication under this section must be provided

information and resources about medication for opioid use disorder and harm reduction strategies and services which may be available, such as substance use disorder treatment services and substance use disorder peer counselors. This information should be available in all languages relevant to the communities that the behavioral health agency serves. Wash. Rev. Code Ann. § 71.24.594.

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This document was developed by Corey Davis, Amy Judd Lieberman, and Kayla Larkin at the Network for Public Health Law's Harm Reduction Legal Project (harmreduction@networkforphl.org). It was originally created in 2021 and has been updated to reflect the state of the law as of January 1, 2023. The legal information provided in this document does not constitute legal advice or legal representation. For legal advice, please consult an attorney in your state.

References

¹ Vital Statistics Rapid Release: Provisional Drug Overdose Death Counts, CENTERS FOR DISEASE CONTROL AND PREVENTION, NATIONAL CENTER FOR HEALTH STATISTICS, <u>https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm</u> (last visited Jan. 15, 2023).

² Press Release, Centers for Disease Control and Prevention (CDC), U.S. Overdose Deaths in 2021 Increased Half as Much as in 2020 – But Are Still Up 15% (May 11, 2022), https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2022/202205.htm ("The new data show overdose deaths involving opioids increased from an estimated 70,029 in 2020 to 80,816 in 2021.")

³ See James M. Chamberlain & Bruce L. Klein, *A Comprehensive Review of Naloxone for the Emergency Physician*, 12 AM. J. EMERGENCY MED. 650 (1994).

 ⁴ Summary Report: Naloxone Economic view, REAGAN-UDALL FOUNDATION FOR THE FOOD AND DRUG ADMINISTRATION, https://reaganudall.org/sites/default/files/2023-03/Naloxone%20Report%20FINAL%203.8.23.pdf (last visited May 23, 2023).
 ⁵ See Eliza Wheeler & Maya Doe-Simkins, Remedy Alliance/For the People distributes over 1 million doses of naloxone in the first 10 months of operation (May 10, 2023), <u>https://remedyallianceftp.org/blogs/news/remedy-alliance-for-the-peopledistributes-over-1-million-doses-of-naloxone-in-the-first-10-months-of-operation;</u> Barrot Lambdin et al., *Identifying Gaps in the Implementation of Naloxone Programs for Laypersons in the United States*, 52 INT'L J. DRUG POL'Y 52 (2018).
 ⁶ Nana Wilson et al., *Drug and Opioid-Involved Overdose Deaths—United States*, 2017–2018, 69 MORBIDITY & MORTALITY WKLY. REP. 290 (2020), https://www.cdc.gov/mmwr/volumes/69/wr/mm6911a4.htm.

⁷ See Deborah Dowell et al., CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016, 65 MORBIDITY & MORTALITY WKLY. REP. 1 (2016), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm; U.S. DEP'T OF HEALTH & HUMAN SERVS., NALOXONE: THE OPIOID REVERSAL DRUG THAT SAVES LIVES, <u>https://www.hhs.gov/opioids/sites/default/files/2018-12/naloxone-coprescribing-guidance.pdf</u> (last visited Jan. 15, 2023).

⁸ See FDA Requiring Labeling Changes for Opioid Pain Medicines, Opioid Use Disorder Medicines Regarding Naloxone, U.S. FOOD & DRUG ADMINISTRATION (Jul. 23, 2020), <u>https://www.fda.gov/news-events/press-announcements/fda-requiring-labeling-changes-opioid-pain-medicines-opioid-use-disorder-medicines-regarding</u>; Corey S. Davis & Derek Carr, Over the Counter Naloxone Needed to Save Lives in the United States, 130 PREVENTATIVE MED.105932 (2020).

⁹ Rebecca L. Haffajee et al., *Legal Requirements and Recommendations to Prescribe Naloxone*, 209 DRUG & ALCOHOL DEPENDENCE 107896 (2020).

¹⁰ While various terms are used in state laws to describe to opioid reversal medication, the term "naloxone" is generally employed in this document for convenience.

¹¹ In this document, "laws" is used to refer to both statutes and administrative regulations that have the force of law. ¹² Prescriber must prescribe (FL, NY, RI, VT, VA, WA); Health care provider must prescribe (NM, IN); Health care professional must prescribe (AZ, AK), practitioner must prescribe (NJ).

¹³ The Illinois law went into effect on January 1, 2023. See 225 Ill. Comp. Stat. Ann. 85/19.1(c); 720 Ill. Comp. Stat. Ann. 570/312(a-10).

¹⁴ Prescriber must offer (CA, SC); Health care prescriber must offer (TN); Physician must offer (OH); Pharmacist must offer (CO, IL, KY).

¹⁵ 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 themself 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.
 ¹⁶ See Ark. Code Ann. § 20-13-1805(d) (a healthcare professional who fails to co-prescribe naloxone may be referred to the appropriate licensing board for administrative sanctions or disciplinary action); Ca. Bus. & Prof. § 742 (a prescriber who fails

to offer a naloxone prescription or fails to provide the education and use information shall be referred to the appropriate licensing board solely for the imposition of administrative sanctions deemed appropriate by that board); S.C. Code Ann. § 44-53-361(B) (a prescriber who fails to offer a prescription or fails to provide the education and use information may be subject to discipline by the appropriate licensing board); Tenn. Code Ann. § 53-11-401(b)(1) (person who fails to comply with coprescribing requirements shall be punishable by a civil penalty assessed by the provider's licensing board and only in cases involving a pattern of willful failure to comply).

¹⁷ 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. 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.
¹⁸ See Florida Stat. § 456.072(mm) (lists "Failure to comply with controlled substance prescribing requirements of s. 456.44" as an act constituting grounds for specified disciplinary actions.); N.J. Admin. Code § 13:35-7.10 (violation of co-prescribing section 13:35–7.6 may be deemed grounds to suspend, deny or revoke a certificate registration or license by the appropriate board.); Ohio Admin. Code 4731-11-02(E)(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.

¹⁹ This table does not include Illinois, as the law in that state, although being passed in 2022, went into effect on January 1, 2023.

²⁰ See Traci C. Green et al., *Laws Mandating Coprescription of Naloxone and Their Impact on Naloxone Prescription in Five US States, 2014–2018,* 110 AM. J. PUB. HEALTH 881 (2020); Minji Sohn et al., *Association of Naloxone Coprescription Laws With Naloxone Prescription Dispensing in the United States,* 2 JAMA NETWORK OPEN e196215 (2019).

²¹ Following an initial administrative order (DCA Administrative Order No. 2020-08, effective May 21, 2020), two New Jersey laws expanded practitioners' co-prescribing requirements: N.J. Admin. Code § 13:35-7.6(f) (effective January 19, 2021) and N.J. Stat. Ann. § 24:21-15.2(j) (effective April 19, 2021).