



# 2023 COSSUP National Forum

Championing The Power of Recovery and Hope

August 29–31, 2023

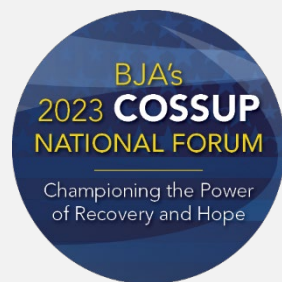
Arlington, Virginia

# Expanding Naloxone Access in Policy and Practice: FDA Action and State Legislation

Jon Woodruff, Esq.  
Managing Attorney

Legislative Analysis and Public Policy Association (LAPPA)

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# Learning Objectives

- After this session, participants will be able to:
  - 1) Analyze the potential **implications of non-prescription naloxone** on third-party payer reimbursement as well statutory provisions regarding standing orders, co-prescribing, and layperson administration.
  - 2) Explain differences between statutory provisions authorizing possession and use of **naloxone at schools** and legislative proposals to require it.
  - 3) Describe **noteworthy legislative proposals** introduced in 2023 designed to increase naloxone access.



# About LAPPA



501(c)(3) nonprofit organization whose mission is to conduct legal and legislative research and analysis and draft legislation on effective law and policy in the areas of public safety and health, substance use disorders, and the criminal justice system.

ONDCP's Model Acts Program Grant recipient for 2019-21, 2021-23, and 2023-25.

[www.legislativeanalysis.org](http://www.legislativeanalysis.org)

# (Some) naloxone-related actions by FDA

- November 2015 – Narcan® nasal spray (Rx form) approved
- April 2019 – First generic (Teva) nasal spray approved
- April 2021 – Kloxxado® (high dose) nasal spray approved
- October 2021 – ZIMHI® single dose injectable approved
- June 2022 – Second generic (Padagis) nasal spray approved
- November 2022 – Preliminary assessment that certain naloxone drug products may be approvable for nonprescription use (up to 4 mg nasal spray and up to 2 mg autoinjector)

# Non-prescription naloxone products

- NARCAN<sup>®</sup> (naloxone hydrochloride) nasal spray, 4 mg/0.1 mL

- ❑ Emergent BioSolutions Inc.
- ❑ FDA approval on March 29, 2023
- ❑ Available “by the late summer [2023]”



#### SOURCES:

- *FDA Approves First Over-the-Counter Naloxone Nasal Spray*, U.S. FOOD AND DRUG ADMINISTRATION (March 29, 2023), <https://www.fda.gov/news-events/press-announcements/fda-approves-first-over-counter-naloxone-nasal-spray>.
- *Marta Sokolowska, PhD, Nonprescription Naloxone: Update and Implications*, 2023 Rx and Illicit Drug Summit presentation (April 11, 2023).
- *U.S. FDA Approves Over-the-Counter Designation for Emergent BioSolutions' NARCAN<sup>®</sup> Nasal Spray, a Historic Milestone for the Opioid Overdose Emergency Treatment*, EMERGENT BIOSOLUTIONS (March 29, 2023), <https://investors.emergentbiosolutions.com/news-releases/news-release-details/us-fda-approves-over-counter-designation-emergent-biosolutions>.

# Non-prescription naloxone products

- RiVive™ (naloxone hydrochloride) nasal spray, 3 mg/0.1 mL
  - ❑ Harm Reduction Therapeutics
  - ❑ FDA approval on July 28, 2023
  - ❑ Available “by early 2024”



#### SOURCES:

- *Harm Reduction Therapeutics and Catalent Sign Commercial Supply Agreement for Naloxone Nasal Spray to Reverse Opioid Overdoses*, CATALENT (March 23, 2023) <https://www.catalent.com/catalent-news/harm-reduction-therapeutics-and-catalent-sign-commercial-supply-agreement/>.
- *RiVive™ is FDA Approved*, Harm Reduction Therapeutics (July 28, 2023), <https://www.harmreductiontherapeutics.org/>

# Questions and implications

- What happens to Rx naloxone market after non-Rx naloxone approved?
- How is Rx naloxone distributed now?
- How do/will individuals pay for Rx/non-Rx naloxone?
- Will non-Rx naloxone affect bulk purchase agreements?
- What are effects on standing orders, co-prescribing requirements, layperson administration, and other provisions in statutes?
- Will Rx(s) for naloxone still be needed?





# What happens to Rx naloxone market?

The approval of OTC Narcan nasal spray will require a change in the labeling for the currently approved 4 mg generic naloxone nasal spray products that rely on Narcan as their reference listed drug product. Manufacturers of these products will be required to submit a supplement to their applications to effectively switch their products to OTC status. The approval may also affect the status of other brand-name naloxone nasal spray products of 4 mg or less, but determinations will be made on a case-by-case basis and the FDA may contact other firms as needed.

FDA Press Release (March 29, 2023)

**SOURCES:**

- *FDA Approves First Over-the-Counter Naloxone Nasal Spray*, U.S. FOOD AND DRUG ADMINISTRATION (March 29, 2023), <https://www.fda.gov/news-events/press-announcements/fda-approves-first-over-counter-naloxone-nasal-spray>.
- *Marta Sokolowska, PhD, Nonprescription Naloxone: Update and Implications*, 2023 Rx and Illicit Drug Summit presentation (April 11, 2023).

# What happens to Rx naloxone market?

- Padagis (naloxone hydrochloride) nasal spray, 4 mg/0.1 mL
  - ❑ First generic non-prescription product
  - ❑ Therapeutic equivalent to NARCAN<sup>®</sup>
  - ❑ FDA approval of labeling supplement announced July 19, 2023



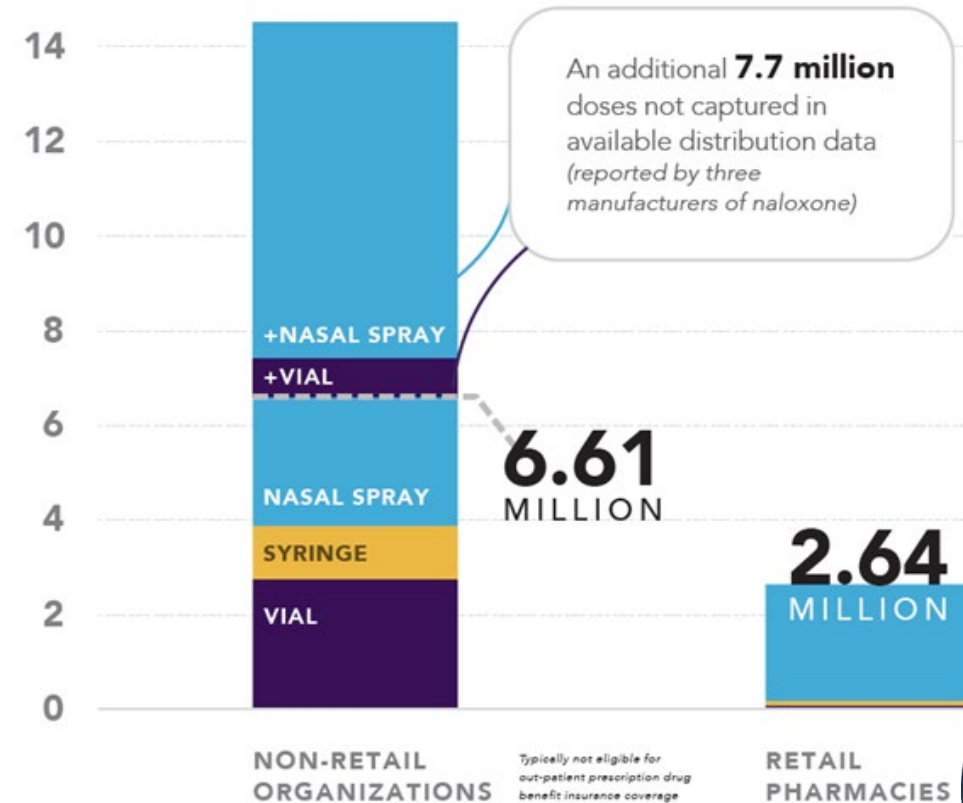
# How is Rx naloxone distributed?

- In 2021, an estimated 16.95 million doses of naloxone distributed
  - 45% missed by distribution data
  - 70% (approx.) nasal spray
  - 16% via retail pharmacies
  - 84% via non-retail avenues

## Naloxone Doses

Distributed in 2021 (IN MILLIONS)

● VIAL  
● SYRINGE  
● NASAL SPRAY



# How do individuals pay for Rx naloxone?

- Non-retail avenues (84%)
  - Donated supplies
  - Negotiated (bulk) purchase agreement
- Retail pharmacies (16%)
  - Cash
  - Pharmacy discount coupons
  - Medicaid/Medicare outpatient Rx drug benefit
  - Private health insurance (with/without copay)

# How will individuals pay for non-Rx naloxone?

- Non-retail avenues (??%)
  - Donated supplies
  - Negotiated (bulk) purchase agreement
- Retail pharmacies (??%)
  - Cash
  - Pharmacy discount coupons (?)
  - Medicaid OTC drug benefit (?)
  - Private health insurance (?)



# How will individuals pay for non-Rx naloxone?

- Medicaid OTC drug benefit
  - Most (all?) state Medicaid plans, plus D.C., cover some OTC medications
  - Product needs to be listed by state as subject to benefit (takes time)
  - Consumer generally required to obtain Rx for product
  - Need for prescriber/pharmacist training
- Medicare
  - No coverage of OTC medications currently
  - Medicare Advantage Plan D may cover OTC medications



**SOURCES:**

- *Summary Report: Naloxone Economic View*, REAGAN-UDALL FOUNDATION FOR THE FOOD AND DRUG ADMINISTRATION, March 2023, [https://reaganudall.org/sites/default/files/2023-03/Naloxone\\_Report\\_FINAL\\_3.10.23.pdf](https://reaganudall.org/sites/default/files/2023-03/Naloxone_Report_FINAL_3.10.23.pdf)
- *Coverage of Over-the-Counter Drugs in Medicaid*, NATIONAL HEALTH LAW PROGRAM (Feb. 1, 2022), <https://healthlaw.org/resource/coverage-of-over-the-counter-drugs-in-medicaid/>.

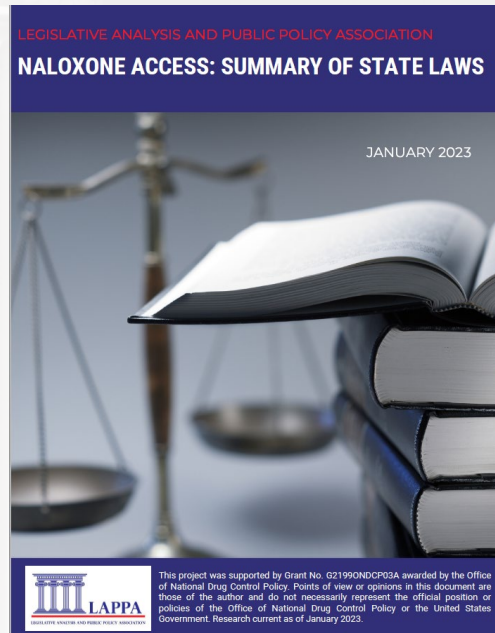
# How will individuals pay for non-Rx naloxone?

- Private insurance
  - Do private insurers cover non-Rx products? If so, when or why?
  - What was the deal with COVID-19 test kits?



# State laws re Medicaid/private insurance

- As of January 2023, 14 states and Puerto Rico place requirements on private health insurers and/or Medicaid re Rx naloxone



Naloxone Access: Summary of State Laws 13

ALABAMA	
Statute(s)	ALA. CODE §§ 20-2-280 to-284
Term(s) used	Opioid antagonist; naloxone.
Initial effective date(s)	June 5, 2015.
Substantive amendment(s) to law(s)	May 10, 2016 amendments allow for: <ul style="list-style-type: none"> <li>Registered nurse in the employment of the state health department or a county health department to dispense naloxone;</li> <li>Member of a fire department, rescue squad, or volunteer fire department personnel to receive a third-party prescription for naloxone; and</li> <li>State Health Officer (SHO) or the respective county health officers to publish a standing order.</li> </ul>
Standing order	The SHO or the respective county health officers have authority to publish a standing order. The SHO issued a statewide standing order on March 8, 2018 as a prescription to obtain naloxone from a pharmacy. The standing order automatically expires on the date naloxone is approved as an over-the-counter medication. <sup>4</sup>
Persons who can prescribe	<ul style="list-style-type: none"> <li>Licensed physician acting in good faith.</li> <li>Licensed dentist acting in good faith.</li> </ul>
Prescriber immunity	The following prescribers are immune from any civil or criminal liability for actions authorized under ALA. CODE §§ 20-2-280 to -284: <ul style="list-style-type: none"> <li>Licensed physician or dentist acting in good faith with no managerial authority over the individuals administering the opioid antagonist; and</li> <li>SHO or any county health officer who issues a standing order.</li> </ul>
Persons who can dispense or distribute <sup>5</sup>	<ul style="list-style-type: none"> <li>Licensed pharmacist.</li> <li>Registered nurse in the state's health department.</li> <li>Registered nurse in a county's health department.</li> </ul>
Dispenser/distributor immunity	Authorized dispensers are immune from any civil or criminal liability for actions authorized under ALA. CODE §§ 20-2-280 to -284.
Persons who can receive or administer ("laypersons")	<ul style="list-style-type: none"> <li>Individual at risk of experiencing an opiate-related overdose.</li> <li>Person in a position to assist an individual at risk of an opioid-related overdose who is:               <ul style="list-style-type: none"> <li>A family member or friend.</li> </ul> </li> </ul>

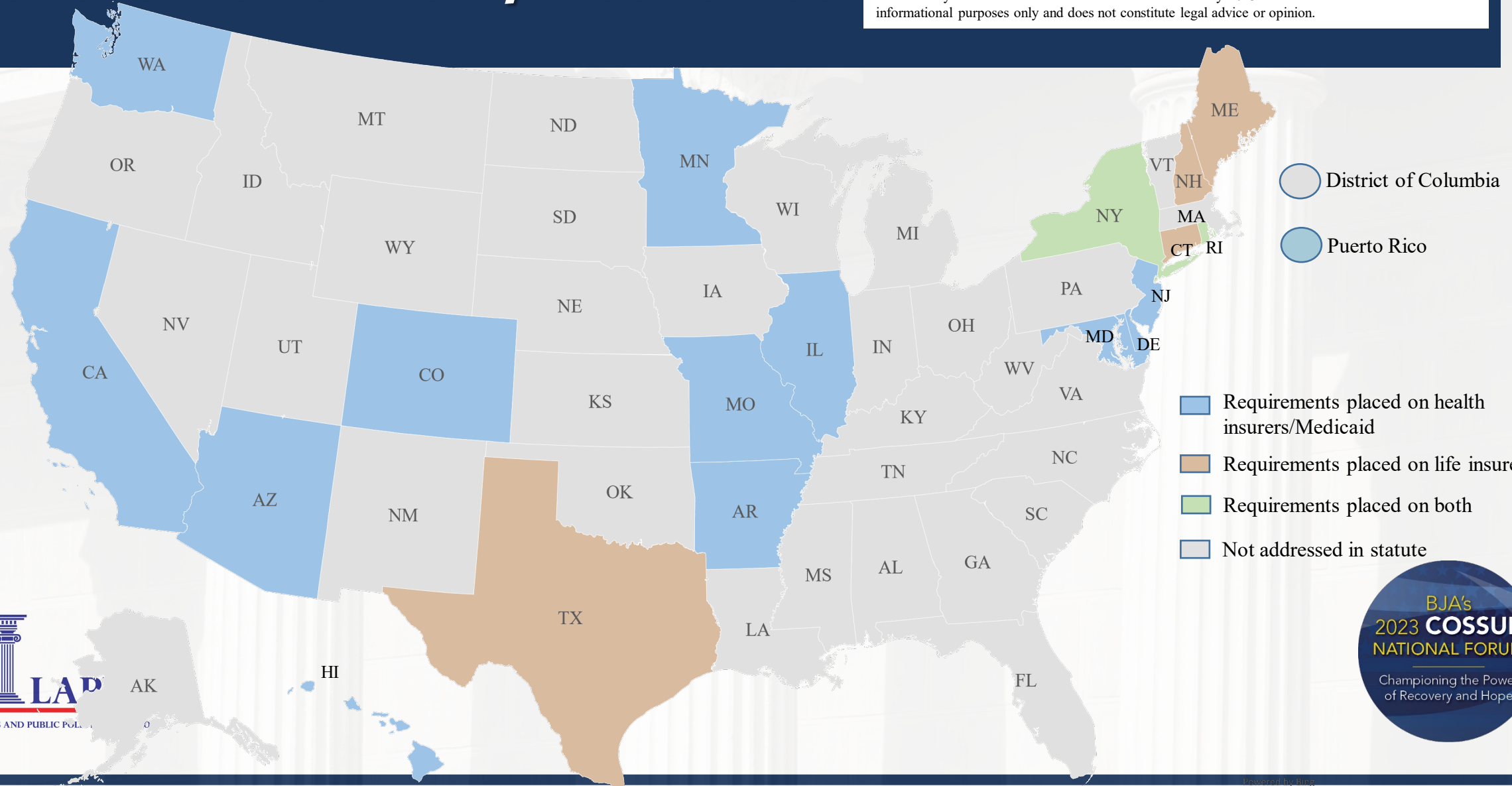
<sup>4</sup> "Standing Order of the State Health Officer Naloxone Distribution for Overdose Prevention," Alabama Dept. of Public Health, accessed May 2022.  
<https://www.alabamapublichealth.gov/pharmacia/assets/naloxonestandingorder.pdf>  
<sup>5</sup> In some jurisdictions, "dispense" is a term of art that applies only to pharmacists or dispensing practitioners. To the extent that naloxone may be provided by other individuals, LAPP uses the terms "distribute" or "provide" in this document.

[Return to Table of Contents](#)



# State laws re Med./insurance

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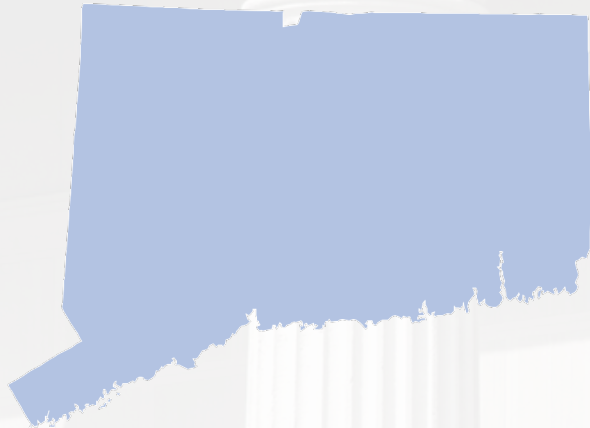


# State laws re Medicaid/private insurance

- Proposed legislation re third party payment for non-Rx naloxone

## [2023 Conn. HB 5809](#)

“To require individual and group health insurance policies to provide health insurance coverage, without prior authorization or a prescription, and regardless of whether naloxone is available over the counter, for not less than one generic opioid device.”



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# State laws re Medicaid/private insurance

- Proposed legislation re third party payment for non-Rx naloxone

## 2023 Cal. AB 1060

Under the bill, prescription or nonprescription naloxone hydrochloride would be a covered benefit under the Medi-Cal program, if that medication is approved, for prescription or nonprescription use, respectively, by the FDA for treatment of an opioid overdose.

The bill would require a health care service plan contract or health insurance policy, as specified, to include coverage for that same medication under the same conditions.

The bill would prohibit a health care service plan contract or health insurance policy from imposing any cost-sharing requirements for that coverage, would prohibit the department from subjecting that coverage to any share-of-cost requirements under the Medi-Cal program, and would require that coverage to include the total cost of that medication.



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# Naloxone access laws and protocols

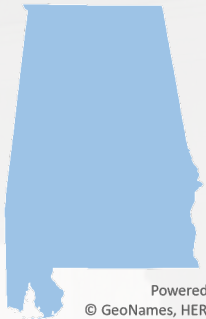
- Standing orders / state protocols / pharmacist authority
- Co-prescription requirements
- Persons with authority to distribute, receive, administer
- Layperson possession and administration
- Training and education requirements
- Reporting dispensing and/or administration

How do provisions written for “naloxone is Rx only” translate to a non-Rx world?



# Standing orders

- All states plus D.C. have method to obtain Rx naloxone without individual Rx
- Are orders product specific?
- Do orders expire upon non-Rx naloxone availability?



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## IX. EXPIRATION AND REVIEW

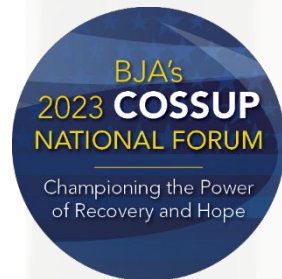
This Standing Order will automatically expire on the date naloxone may be approved as an over-the-counter medication. This Standing Order will be reviewed, and may be updated, if there is relevant new science about naloxone administration and will be posted at <http://www.alabamapublichealth.gov>, search naloxone.

## XI. Expiration and review

This standing order will automatically expire one year from the date of authorization, or the date naloxone may be approved as an over-the-counter medication, whichever occurs first. It may be reissued annually at the discretion of the medical director. This standing order will be reviewed, and may be updated, if there is relevant new science about naloxone administration.



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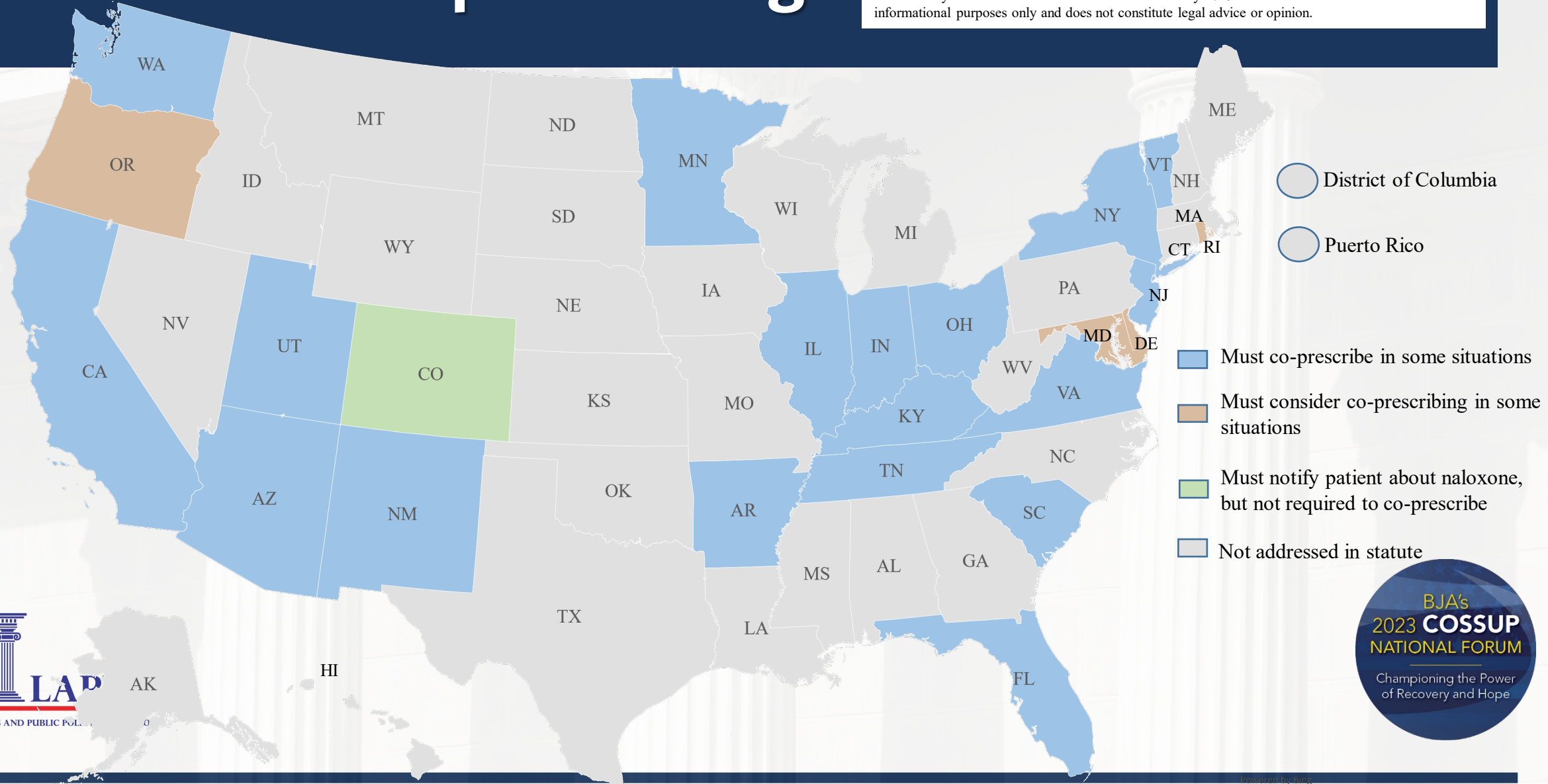


# State laws re co-prescribing

- As of July 2023, 23 states have laws related to co-prescribing naloxone along with an opioid prescription

# State laws re co-prescribing

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# State laws re co-prescribing

- As of July 2023, 23 states have laws related to co-prescribing naloxone along with an opioid prescription
- In 18 states, co-prescribing is required in certain cases
- This suggests:
  - Prescriptions for naloxone will continue
  - Need for prescriber/pharmacist training about continuation of Rx(s)
  - Need for policymakers to consider: (1) how (or if) to change co-prescribing laws and (2) ways to encourage patients with opioid prescriptions to obtain non-Rx naloxone



# State laws re layperson administration

- GA. CODE ANN. § 26-4-116.2(d) (West 2023)
- “A person acting in good faith and with reasonable care to another person whom he or she believes to be experiencing an opioid related overdose may administer an opioid antagonist **that was prescribed pursuant to subsection (b) of this Code section in accordance with the protocol specified by the practitioner or pursuant to Code Section 31-1-10”**



Prescription from practitioner

Standing order

# Naloxone in schools

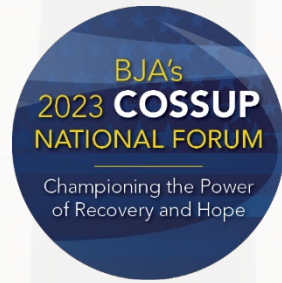
"A colleague and I are currently writing about legislation ... that would require middle and high schools in the state to stock at least two doses of naloxone....

Do you know how many states require schools to keep naloxone on hand?"



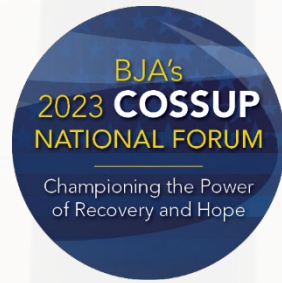
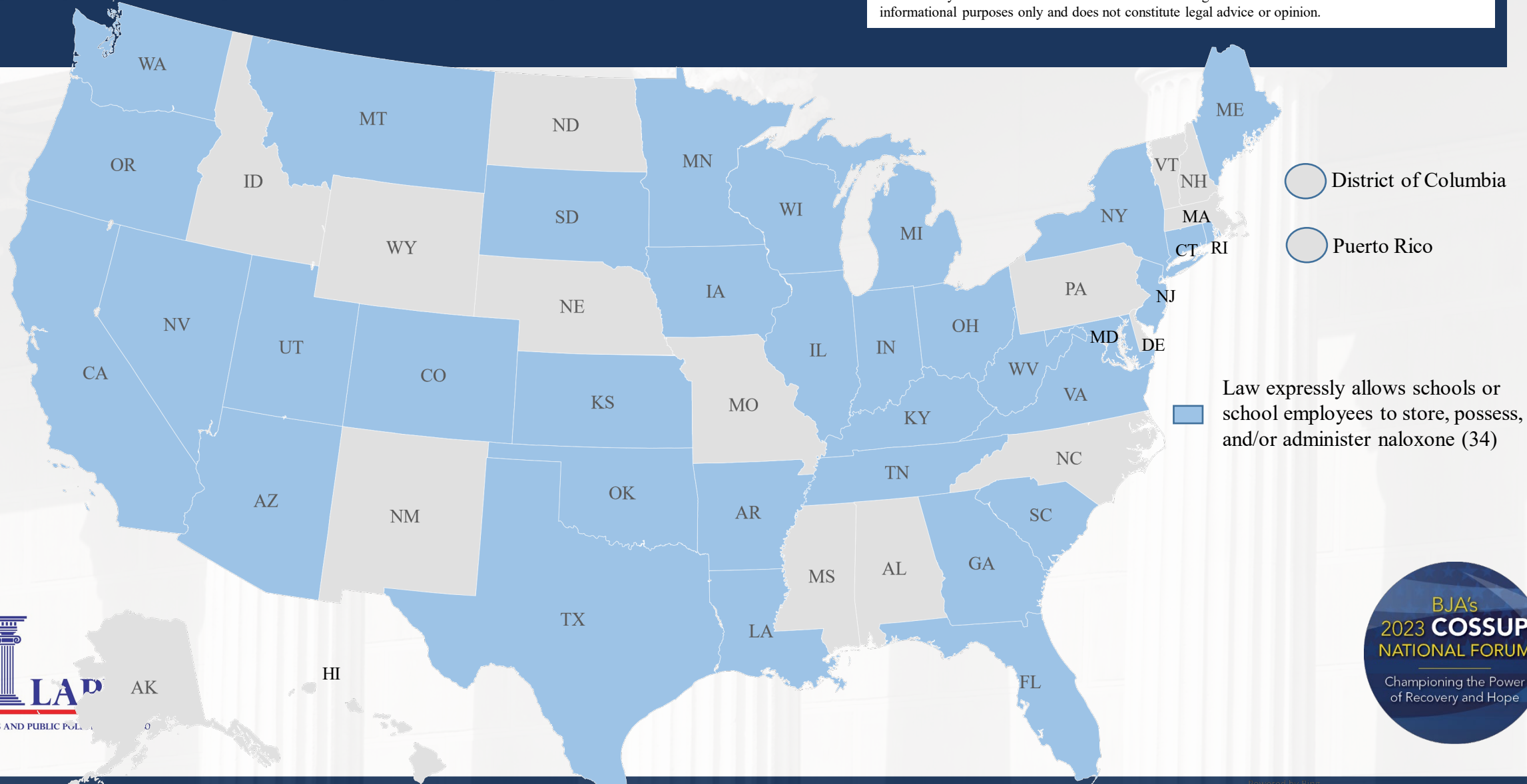
# Naloxone in schools

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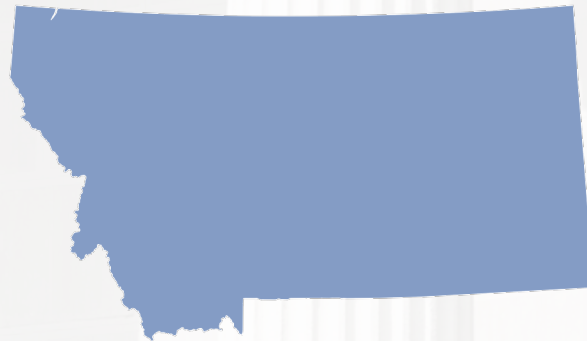
# Naloxone in schools

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# Naloxone in schools

(1) A school, whether public or nonpublic, may maintain a stock supply of an opioid antagonist to be administered by a school nurse or other authorized personnel to any student or nonstudent as needed for an actual or perceived opioid overdose. A school that intends to obtain an order for emergency use of an opioid antagonist in a school setting or at related activities shall adhere to the following requirements:



MONT. CODE ANN. § 20-5-426 (West 2023)

# Naloxone in schools

M. The governing authority of each public and nonpublic elementary and secondary school may adopt a policy that authorizes a school to maintain a supply of naloxone or other opioid antagonists and authorizes a school nurse or other school employee to administer naloxone or another opioid antagonist to any student or other person on school grounds in the event of an actual or perceived opioid emergency. Such a policy shall require that school employees other than school nurses receive at least six hours of general training, including training on emergency administration, from a registered nurse or a licensed medical physician prior to being authorized to perform such administration. A school governing authority that does not adopt such a policy shall not be subject to civil liability for failing to authorize such supply or administration.

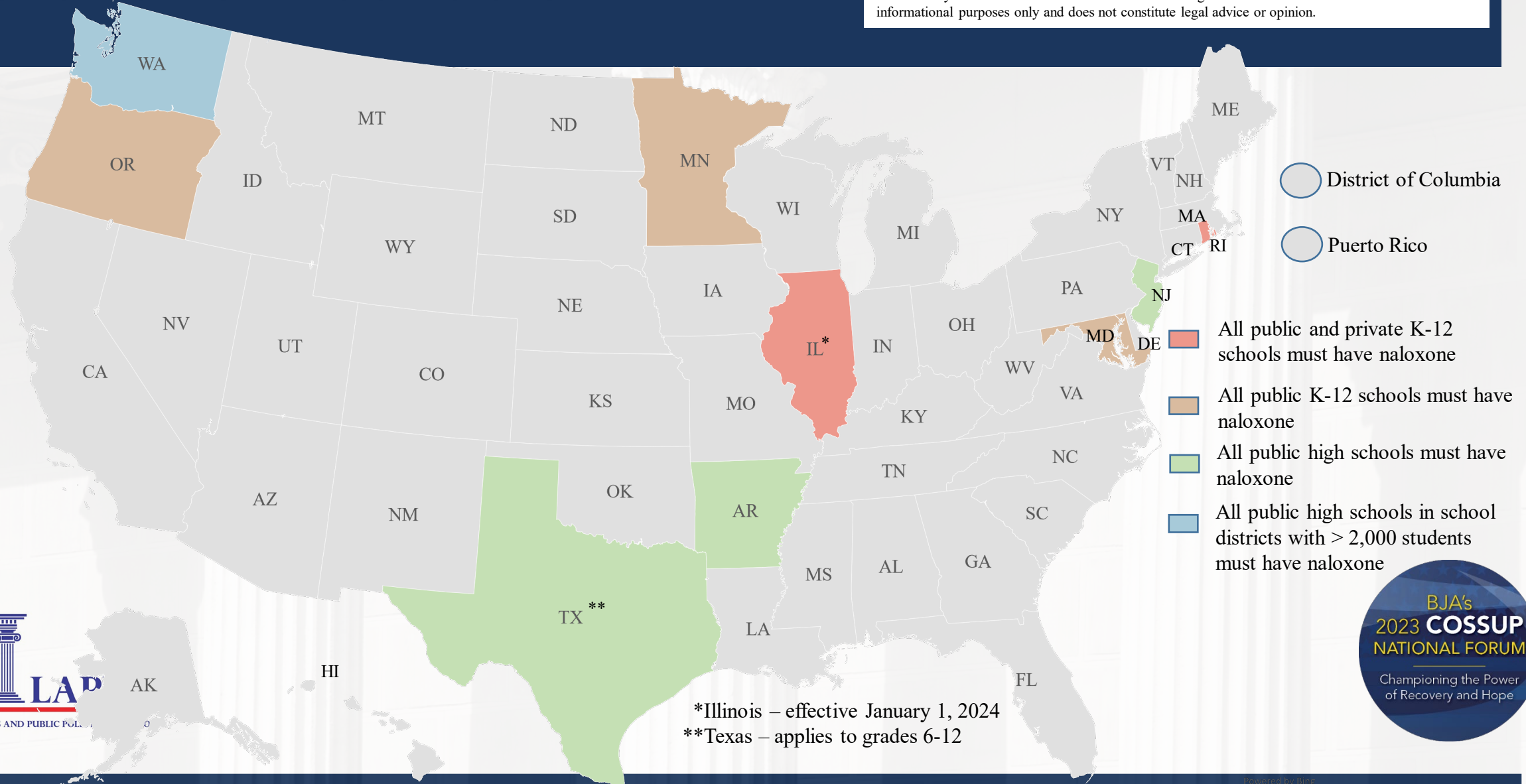
LA. STAT ANN.  
§ 17:436.1 (West 2023)



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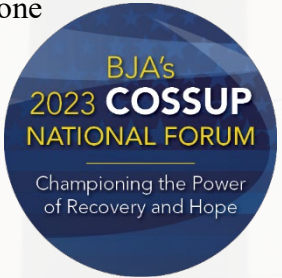
# Naloxone in schools

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- District of Columbia
- Puerto Rico
- All public and private K-12 schools must have naloxone
- All public K-12 schools must have naloxone
- All public high schools must have naloxone
- All public high schools in school districts with > 2,000 students must have naloxone

\*Illinois – effective January 1, 2024  
\*\*Texas – applies to grades 6-12



# Naloxone in schools

(b) All public and private elementary, middle schools, junior high schools, and high schools, shall provide and maintain on-site in each school facility opioid antagonists, as defined herein.



R.I. GEN. LAWS ANN.  
§ 16-21-35 (West 2023)



# Naloxone in schools

(a) Each school district shall adopt and implement a policy regarding the maintenance, administration, and disposal of opioid antagonists at each campus in the district that serves students in grades 6 through 12 and may adopt and implement such a policy at each campus in the district, including campuses serving students in a grade level below grade 6.

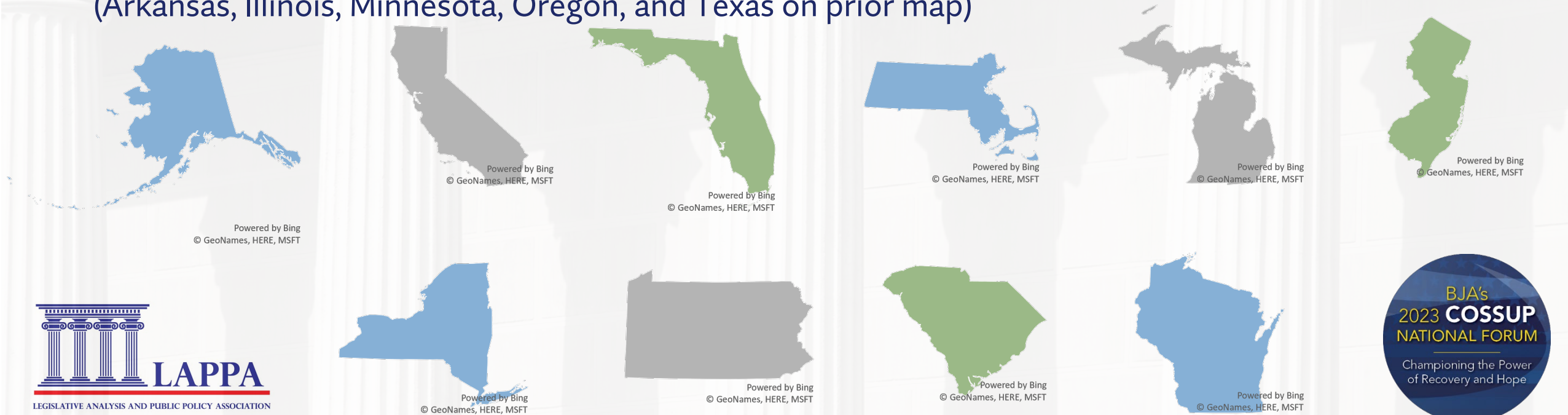
(c) A policy adopted under this section must:

(3) establish the number of opioid antagonists that must be available at each campus at any given time; and

TEX. EDUC. CODE  
§ 38.222 (West 2023)

# Naloxone in schools

- ≈45 bills in 2023 legislative session; 30% enacted
- Bills in 15 states proposed to require naloxone in at least some schools (Arkansas, Illinois, Minnesota, Oregon, and Texas on prior map)



# Noteworthy 2023 legislation

- ≈120 bills in 2023 legislative session; 25% enacted

# Noteworthy 2023 legislation - enacted

- Manufacturing low-cost naloxone



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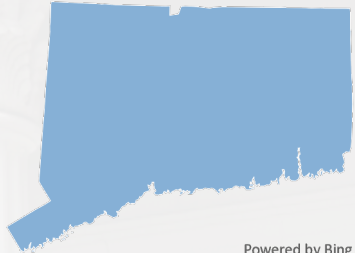
## [2023 Cal. SB 101](#)

Budget Act of 2023.

Approximately \$30,000,000 appropriated for encumbrance or expenditure until June 30, 2028, to implement the CalRx Naloxone Access Initiative to support the **development and manufacture of an at-cost or near-cost generic version of a naloxone nasal spray product.**

# Noteworthy 2023 legislation - enacted

- Access in public venues – requiring or authorizing box



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“Secure box”  
placed in public  
location



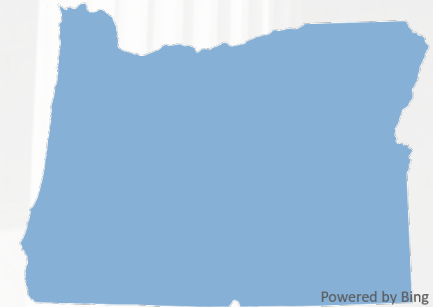
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Music venues



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Wall-mounted box  
on municipality  
property



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Publicly  
accessible  
building

# Noteworthy 2023 legislation - enacted

- Allowing coroners to administer → South Carolina
- Allowing LE to distribute multiple kits → Oregon
- Co-prescribing → New Mexico, South Carolina, Utah
- Corrections → Virginia
- Expanding administration, removing training for possession, and requiring statewide plan → Virginia

# Noteworthy 2023 legislation - enacted

- Expanding liability protection → California, Maine
- Expanding who may be prescribed → Arkansas, Iowa
- Removing data collection from PDMP → Oregon
- Requiring first responders to use it → Maine

# Noteworthy 2023 legislation - proposed

- Study on protecting access → Congress (S.1373)
- Access in public places → California, Connecticut, New York, Tennessee
- Bulk purchase fund for schools → Colorado
- Bulk purchase fund generally → Illinois, Texas
- Co-pay assistance fund → Connecticut
- Develop data system re administration and OD deaths → Oregon
- Equipping first responders → Connecticut, Massachusetts, Oregon, Pennsylvania



# Noteworthy 2023 legislation - proposed

- Harm reduction training for LEs → Virginia
- Income tax credit for purchasing → Oklahoma
- Insurance coverage → California, Connecticut, Massachusetts, New York
- Outreach to tribal governments → California
- Providing 8mg supply kits to substance use providers → Illinois

# Noteworthy 2023 legislation - proposed

- Reporting administration to PDMP → New York
- Requiring hospitals to provide → Oklahoma (vetoed)
- Requiring corrections to provide → Oklahoma (vetoed)

# Questions and Answers



# Contact Information

**Jon Woodruff, Esq.  
Managing Attorney**

**Legislative Analysis and Public Policy Association**

**[jwoodruff@thelappa.org](mailto:jwoodruff@thelappa.org)**

**434.252.3303**

