

THE LEGISLATIVE ANALYSIS AND PUBLIC POLICY ASSOCIATION

Nonprescription Naloxone: Update and Implications

National Governors Association – Opioid State Action Network

May 18, 2023

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Legislative Analysis and Public Policy Association (LAPPA)

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 and 2021-23.

www.legislativeanalysis.org

FDA notice/request

- November 16, 2022
- Preliminary assessment by FDA that certain naloxone drug products may be approvable as safe and effective for nonprescription use
- Up to 4 milligrams (mg) nasal spray and up to 2 mg autoinjector for intramuscular (IM) or subcutaneous (SC) use
- Asks for comments by January 17, 2023



FEDERAL REGISTER

The Daily Journal of the United States Government



 Notice

Safety and Effectiveness of Certain Naloxone Hydrochloride Drug Products for Nonprescription Use; Request for Comments

A Notice by the Food and Drug Administration on 11/16/2022



Nonprescription naloxone products

- NARCAN[®] (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[®] 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>.

Nonprescription naloxone products

- RiVive™ (naloxone hydrochloride) nasal spray, 3 mg/0.1 mL
 - ❑ Harm Reduction Therapeutics
 - ❑ FDA priority review granted December 26, 2022
 - ❑ FDA approval anticipated “in July 2023”
 - ❑ Product launch “in early 2024”



SOURCE:

- *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/>.

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, other provisions in statutes?
- Will Rxs for naloxone still be necessary even if there is no Rx naloxone?



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)

- “Other formulations (e.g., injectables) and dosages will remain Rx only”

SOURCE:

- *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).

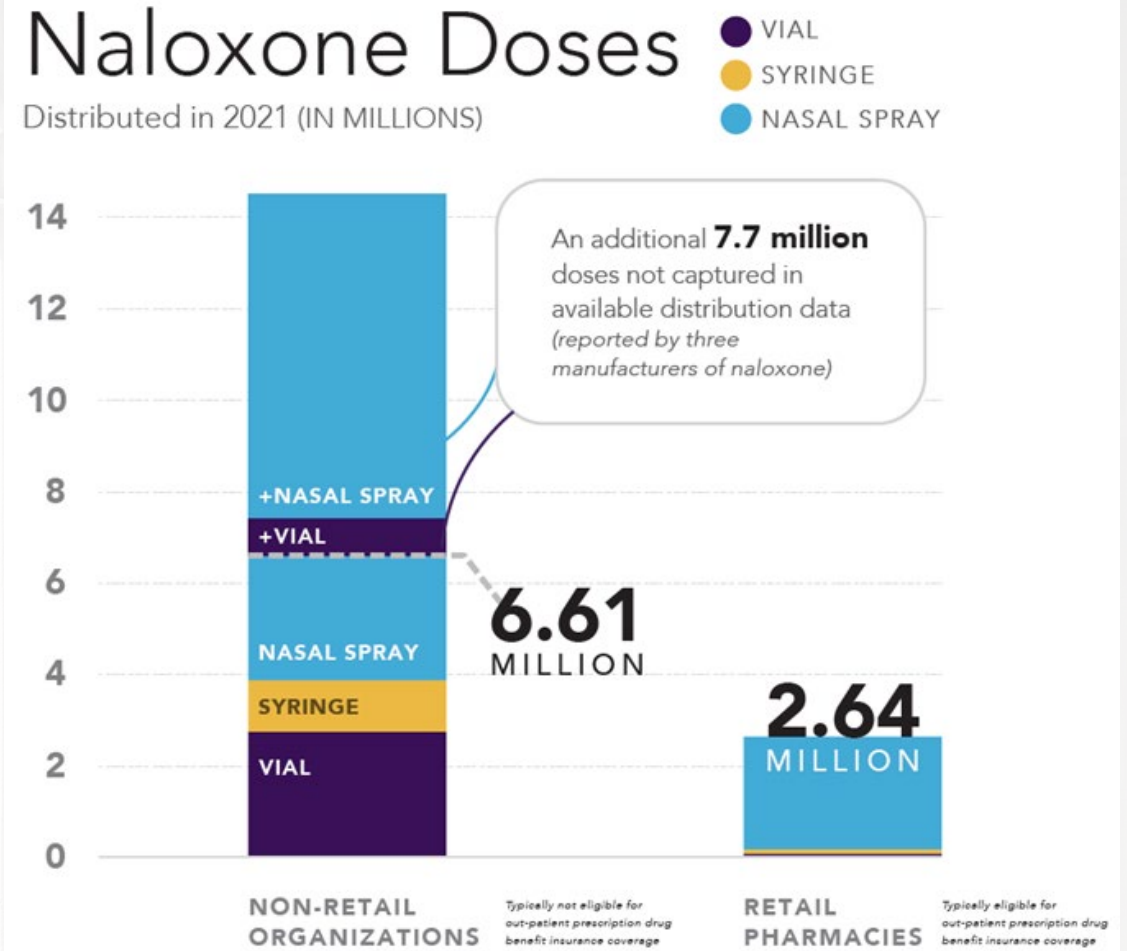
How is Rx naloxone distributed?



Summary Report: Naloxone Economic View, REAGAN-UDALL FOUNDATION FOR THE FOOD AND DRUG ADMINISTRATION, March 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



SOURCE:

- 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>

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 (84% (?))
 - 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
- Will federal or state legislators step in?



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>
- 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?
- Will federal or state legislators step in?

STAT @statnews · May 16
EXCLUSIVE: The White House is summoning naloxone manufacturers for a roundtable focused on the medication's price.

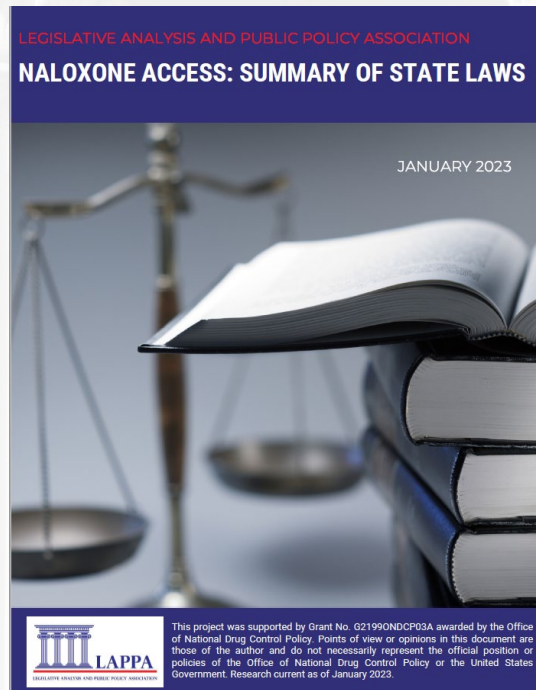


statnews.com
Biden drug czar to summon naloxone makers to White House to disc...
The White House drug czar is summoning naloxone makers for a meeting to address the price of naloxone, a medication used to ...

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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"> Registered nurse in the employment of the state health department or a county health department to dispense naloxone. Member of a fire department, rescue squad, or volunteer fire department personnel to receive a third-party prescription for naloxone; and State Health Officer (SHO) or the respective county health officers to publish a standing order.
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. ⁴
Persons who can prescribe	<ul style="list-style-type: none"> Licensed physician acting in good faith. Licensed dentist acting in good faith.
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"> Licensed physician or dentist acting in good faith with no managerial authority over the individuals administering the opioid antagonist; and SHO or any county health officer who issues a standing order.
Persons who can dispense or distribute⁵	<ul style="list-style-type: none"> Licensed pharmacist. Registered nurse in the state's health department. Registered nurse in a county's health department.
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"> Individual at risk of experiencing an opiate-related overdose. Person in a position to assist an individual at risk of an opioid-related overdose who is: <ul style="list-style-type: none"> A family member or friend.

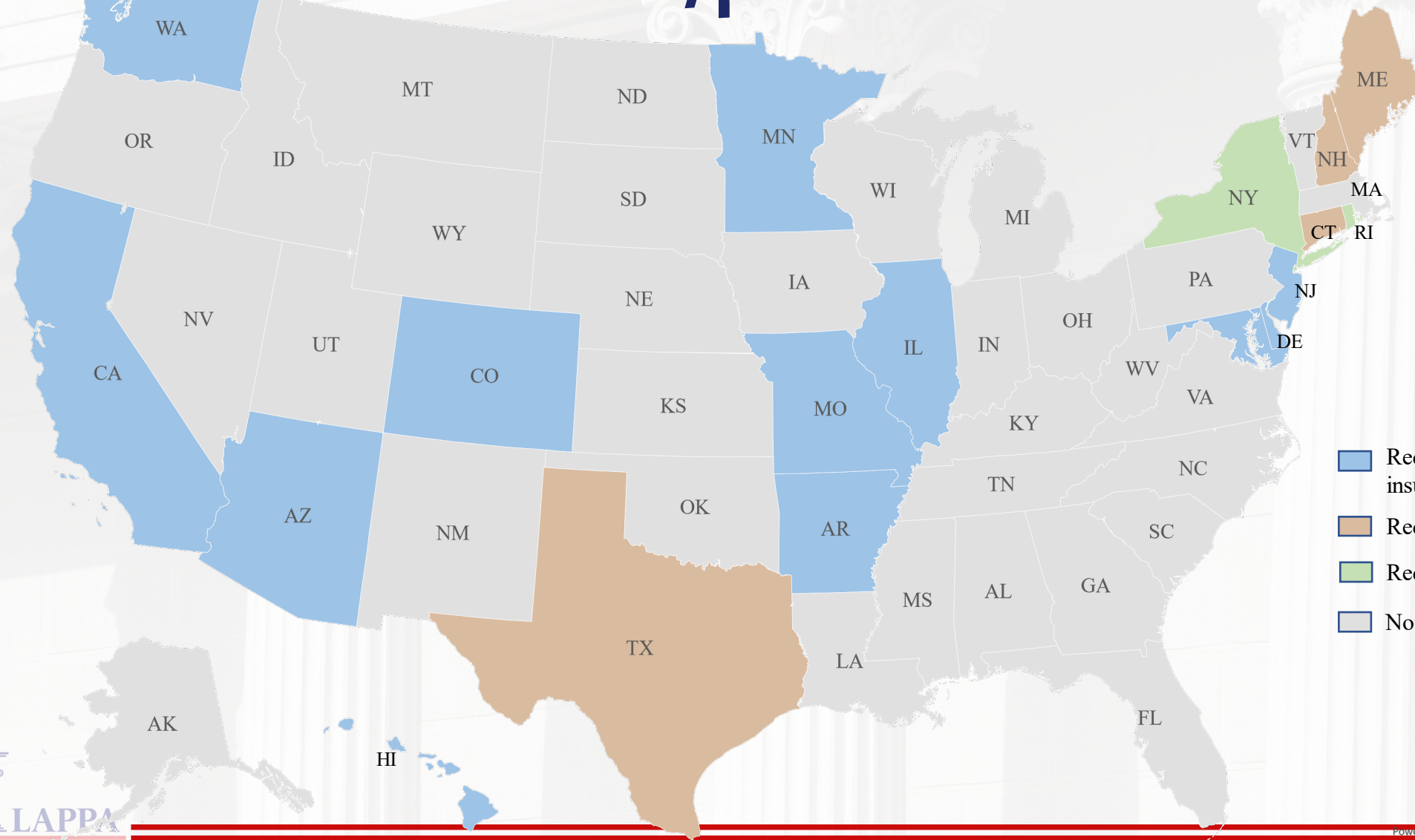
⁴ "Standing Order of the State Health Officer Naloxone Distribution for Overdose Prevention," Alabama Dept. of Public Health, accessed May 2022, <https://www.alabamapublichealth.gov/pharmacy/assets/naloxonestandingorder.pdf>.
⁵ In some jurisdictions, "dispense" is a term of art that applies only to pharmacists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

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SOURCE:

- Naloxone Access: Summary of State Laws, LEG. ANALYSIS & PUB. POLICY ASSOC. (January 2023), <https://legislativeanalysis.org/naloxone-summary-of-state-laws/>.

State laws re Medicaid/private insurance



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- District of Columbia
- Puerto Rico

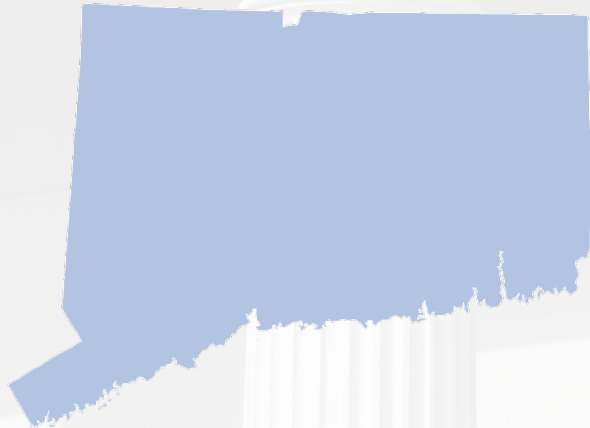
- Requirements placed on health insurers/Medicaid
- Requirements placed on life insurers
- Requirements placed on both
- Not addressed in statute

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.

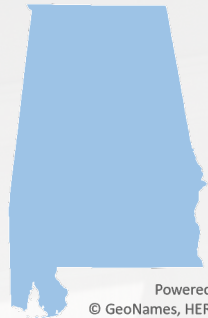
The bill would prohibit a health care service plan contract or health insurance policy from imposing any cost-sharing requirements for that coverage, would prohibit the department from subjecting that coverage to any share-of-cost requirements under the Medi-Cal program, and would require that coverage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



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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.



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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.

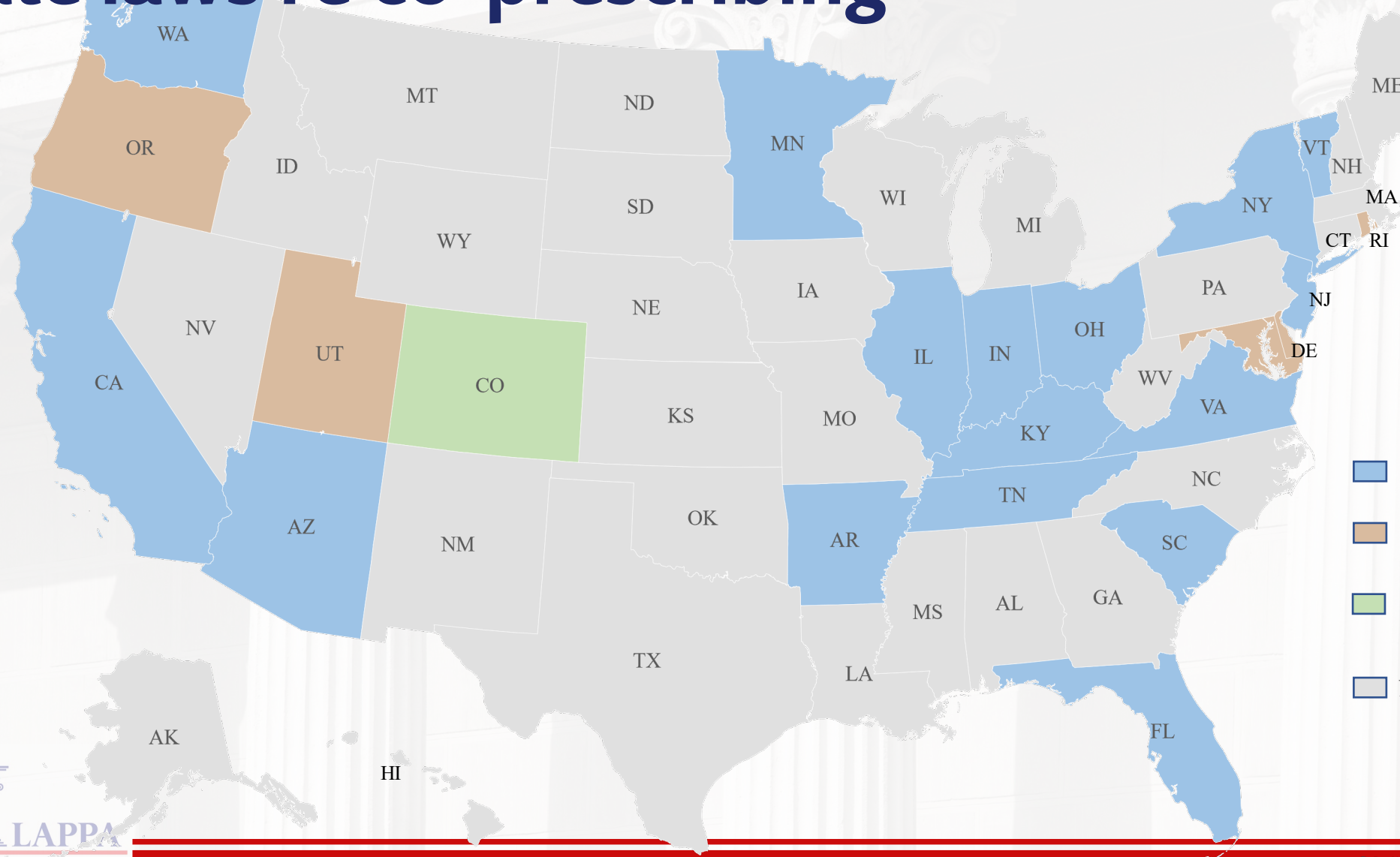
State laws re co-prescribing

- As of January 2023, 22 states have laws related to co-prescribing naloxone along with an opioid prescription

SOURCE:

- *Naloxone Access: Summary of State Laws*, LEG. ANALYSIS & PUB. POLICY ASSOC. (January 2023), <https://legislativeanalysis.org/naloxone-summary-of-state-laws/>.

State laws re co-prescribing



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- District of Columbia
- Puerto Rico

- Must co-prescribe in some situations
- Must consider co-prescribing in some situations
- Must notify patient about naloxone, but not required to co-prescribe
- Not addressed in statute

State laws re co-prescribing

- As of January 2023, 22 states have laws related to co-prescribing naloxone along with an opioid prescription
- In 16 states, co-prescribing is required in certain cases
- This suggests:
 - Prescriptions for naloxone will continue
 - Need for prescriber/pharmacist training about continuation of Rx for naloxone
 - 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

SOURCE:

- *Naloxone Access: Summary of State Laws*, LEG. ANALYSIS & PUB. POLICY ASSOC. (January 2023), <https://legislativeanalysis.org/naloxone-summary-of-state-laws/>.

State laws re layperson administration

- GA. CODE ANN. § 26-4-116.2(d) (West 2022)
- “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

Buying process

- Fewer barriers to access (potentially)
 - Don't have to talk to someone at pharmacy counter
 - No applying “limitations” from standing order
 - Less confusion about who may purchase?
- Does it go “behind-the-counter”?
- Training for administration (how much is necessary?)
- Individuals likely will still need prescriptions for naloxone

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