Nonprescription Naloxone: Update and Implications
National Governors Association – Opioid State Action Network
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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
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:
- Marta Sokolowska, PhD, Nonprescription Naloxone: Update and Implications, 2023 Rx and Illicit Drug Summit presentation (April 11, 2023).
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:
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:
• 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:
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 (?)

≈ $50 Product Cost
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:
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?
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

SOURCE:
State laws re Medicaid/private insurance

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

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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.”
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.
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?

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.
State laws re co-prescribing

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

SOURCE:
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:
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”
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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