Nasal Naloxone is Available Over The Counter

(But people still need help to get it)

OVER-THE-COUNTER NALOXONE

PRODUCTS

Narcan Nasal Spray 4 mg/0.1 mL (Emergent)

Naloxone 4 mg/0.1 mL nasal spray (generics)

RiVive 3 mg/0.1 mL (Harm Reduction Therapeutics)

NaxSwab OTC (Pocket Naloxone) — *Coming Soon!*

AVOIDING ACCESS BARRIERS

- Know the location of OTC naloxone in your pharmacy and educate non-pharmacy staff
- Staff and signage should tell patients that pharmacy can help with OTC naloxone training and cost
- Be familiar with free sources of naloxone in your community

ADDRESSING COST

Process OTC naloxone as a prescription to bill insurance and discount programs

- Continue to encourage providers to prescribe opioid antagonists
- Use your protocol to initiate a prescription
  No protocol? Use the link below to learn how to become opioid antagonist certified and dispense naloxone by protocol
- KY Medicaid has indicated they will cover OTC naloxone at $0 copay
- Use the Kentucky Naloxone Copay Program
  ID: 1396065983 **Bin:** 610524
  Group: 50778063 **PCN:** Loyalty

LEARN MORE AND EARN CE

Scan the QR code or visit https://healky.learningexpressce.com to access more resources and participate in a free 1-hour continuing education activity about opioid antagonists for overdose rescue

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Stopping Chronic Opioid Therapy Has Risks

(Use caution when deciding to fill or refuse an Rx)

OPIOID TAPERING AND DISCONTINUATION

WHAT IS THE RISK?

- Overdose death and suicide are more common when chronic opioid therapy is discontinued than when opioid therapy is maintained;[1,2] tapering is associated with a small absolute increase in the risk of overdose or suicide[3]
- The risk of death after stopping opioids increases with longer treatment duration and is highest immediately after discontinuation[2]
- Patients on stable, longer-term, higher-dose opioid therapy have an increased risk of mental health crisis (e.g., depression, anxiety, suicide attempt) encounters with opioid tapering, which increases with faster tapering[4]
- Rapid reduction or abrupt discontinuation of high-dose, long-term opioid therapy increases the risk of overdose and incident OUD[5]

RECOMMENDATIONS

- The 2022 CDC guideline recommends continuing opioids when benefits outweigh risks; detailed advice is provided for gradual, patient-centered tapering when risks outweigh benefits[6]
- The FDA has issued a warning against sudden discontinuation of opioid pain medicines:[7]
  - Do not abruptly discontinue opioid analgesics in patients physically dependent on opioids
  - Counsel patients not to discontinue their opioids without first discussing the need for a gradual tapering regimen
  - There are no standard opioid tapering schedules that are suitable for all patients. Create a patient-specific plan and ensure ongoing monitoring and support

REFERENCES

1. James JR, et al. *J Gen Intern Med*. 2019 Dec;34(12):2749-2755; **2.** Oliva EM, et al. *BMJ*. 2020;368:m283; **3.** Larochelle MR, et al. *JAMA Netw Open*. 2022;5(8):e2226523; **4.** Agnoli A, et al. *JAMA*. 2021 Aug 3;326(5): 411-419; **5.** DiPrete BL, et al. *JAMA Netw Open*. 2022 Apr 1;5(4):e229191; **6.** Dowell D, et al. *MMWR Recomm Rep*. 2022;71(No. RR-3):1–95; **7.** FDA Drug Safety Communication, 4/9/2019

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Partial Fills are OK for Schedule II Drugs

(If you follow the DEA's rules)

PARTIAL FILLS OF SCHEDULE II CONTROLLED SUBSTANCES

21 CFR 1306.13 has been amended to align with CARA 2016; Kentucky's **902 KAR 55:095** contains similar provisions

PARTIAL FILL REQUESTS

A partial fill of a CII Rx may be requested by a:

- Patient, parent or legal guardian of a minor, or a caregiver with power of attorney; the request can be made in person, by phone, or in writing (must be signed)
- Prescriber by indicating the partial quantities to dispense on the prescription or in consultation with the pharmacist

PHARMACIST DOCUMENTATION

If not already indicated on the prescription, the pharmacist must note one of the following:

- The [patient, parent or legal guardian of a minor patient, or caregiver of an adult patient named in a medical power of attorney] requested partial fill on [date]
- "Authorized by Practitioner to Partial Fill," the name of the practitioner, the date and time of the discussion, and the pharmacist's initials

Record all typical dispensing information with each partial fill, including quantity dispensed, date dispensed, and dispensing pharmacist

OTHER REQUIREMENTS

- Remaining portions must be filled no later than 30 days after the **written date** of the prescription
- An individual can request less medication than the prescriber's specified quantity but not more
- The total quantity dispensed in all partial fillings cannot exceed the total quantity prescribed
- The prescription must be written in accordance with all federal and state regulations

Notes: Information does not apply to partial fills related to product availability, hospice, or long-term care. This is not legal advice. Refer to state and federal law for details.

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DEA Permits Transfer of All CS Prescriptions

(But the Rx has to stay fully electronic)

TRANSFER OF CONTROLLED SUBSTANCE RX FOR INITIAL FILLING

The DEA amended **21 CFR 1306.08** to explicitly state that an electronic prescription for a controlled substance in schedule II–V may be transferred between pharmacies for initial filling upon request from the patient.

TRANSFER REQUIREMENTS

The prescription must remain in ***electronic form***

Transfer of a controlled substance prescription may occur on a one-time basis only

Transfer must be communicated directly between two licensed pharmacists

The legally required contents of the prescription must be unaltered during the transmission

DOCUMENTATION

Both the transferring and receiving pharmacist must record the following:

- That prescription was transferred
- Name, address, and DEA number of the pharmacy to/from which the prescription was transferred
- Names of the pharmacists receiving and transferring the prescription;
- Date of the transfer

Prescription processing software may capture information from the electronic prescription and automatically populate corresponding data fields to document the transfer

Maintain documentation of transfer for 2 years

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Notes: Information applies only to initial fills. DEA has not changed 21 CFR 1306.25, which permits the transfer of paper, oral, or electronic prescriptions in Schedules III, IV, and V for refill dispensing. This is not legal advice. Refer to state and federal law for details.

Pharmacies Have a Role in Drug Disposal

(Because leftover opioids can put people at risk)

THE PHARMACY'S ROLE IN MEDICATION DISPOSAL

DRUG DISPOSAL FACTS

- About half of people who misused pain relievers reported the source was "given by, bought from, or took from a friend or relative"
- Vulnerable household members may access leftover opioids, leading to accidental overdose
- Proper disposal keeps drugs out of soil and water
- The FDA and EPA both recommend promptly disposing of unused, unwanted, and expired medication at a take-back event or permanent disposal receptacle

LEGAL REQUIREMENT

KRS 218A.170 requires pharmacists to inform patients about the importance of proper and safe disposal when dispensing a prescription for an opioid, benzodiazepine, barbiturate, codeine, or amphetamine

The pharmacist or designee may inform patients verbally, in writing, or via posted signage

FIND DISPOSAL LOCATIONS

Scan the QR code to access the DEA's Controlled Substance Public Disposal Locations database; local law enforcement agencies may also offer a public disposal receptacle

COMING IN 2024

The FDA is updating its opioid REMS program to encourage opioid disposal

When implemented, pharmacies will have the option to order prepaid mail-back envelopes from opioid manufacturers, which they can then provide to patients prescribed opioid analgesics

Wholesalers may be able to provide more information about how and when opioid disposal programs will roll out

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