Buprenorphine Barriers
Red Flags

Red flag is a DEA term describing "circumstances surrounding a prescription that cause a pharmacist to take pause, including signs of diversion or the potential for patient harm."

The DEA says: *The presence of a red flag itself does not mean that a pharmacist cannot fill a prescription.* Corresponding responsibility requires that the pharmacist address, resolve, and make a record of the resolution of each red flag prior to dispensing. DEA enforcement actions focus on sustained patterns of questionable dispensing with unresolved red flags.

Red flags require professional judgment.

Even what constitutes a red flag can change depending on the characteristics of the drug, the patient, and the community.

Reference: Gulf Med Pharmacy; Decision and Order, 86 Fed. Reg. 72,694, 72,703 (Dec. 22, 2021).

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Resolving Red Flags

1. Identify a red flag, considering context such as drug, patient, prescriber, community, etc.

2. Gather information through one or more source:
   - Patient's profile, history, and KASPER report
   - Patient or caregiver
   - Pre-existing knowledge of pharmacy staff
   - Prescriber
   - Other available data or information

3. Decide whether to fill fully, partially, or not at all. If red flags are resolved, dispensing is appropriate.

4. Document relevant information and the resolution of red flags. (Must explain beyond "verified" or "OK per prescriber.")
   - If relevant to single prescription, append prescription record

     (Per Dr. Smith, dose increased last week, early fill at new dose appropriate. -MR, RPh, 8/29/2024)

   - If relevant to future prescriptions, add note to patient profile to be reviewed with each fill

     (Address out of state; patient staying with parents here to access OUD treatment. -LS, RPh, 9/25/2024)

5. When choosing not to dispense, document and communicate promptly and thoroughly with patient and prescriber. Attempt to mitigate risks to patient.

Buprenorphine Barriers

Suspicious Order Monitoring

The DEA does not limit the quantity of controlled substances that can be ordered or dispensed. The federal Controlled Substances Act requires manufacturers and distributors to monitor for and report **suspicious orders**, including "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."

In 2021, AmerisourceBergen (now Cencora), Cardinal Health, and McKesson entered legal settlements that require controlled substance monitoring programs (CSMPs), metrics related to specific red flags, and thresholds to identify potentially suspicious orders.

Distributors are prohibited from sharing threshold information with their customers. However, all three distributors allow pharmacies to request modification of thresholds to meet the needs of patients.

Notably, buprenorphine is **not** among the "highly diverted controlled substances" that are the focus of the distributors' CSMPs. Buprenorphine monoproduct is considered a "high-risk formulation."

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Should pharmacies try to manage ordering thresholds for buprenorphine?

The *PhARM-OUD Guideline* cautions that "pharmacists should neither attempt to guess their distributor thresholds nor should they assume that crossing a threshold will result in adverse legal consequences."

When should pharmacies request a threshold increase from a distributor?

Distributors must conduct extensive reviews when a pharmacy requests a threshold increase. Consider contacting a distributor to begin this process when:

- Buprenorphine order canceled by distributor
- OUD treatment clinic opens or expands nearby
- Pharmacy accepts new patient population or offers new service related to OUD
- Pharmacy rations buprenorphine or modifies prescriptions due to low or out of stock products
- Pharmacy growth in buprenorphine dispensing is disproportionate to growth of other products

Will buprenorphine ordering ever get easier?

Concerns about suspicious order monitoring have been documented and advocacy is underway to address barriers to care. The DEA has encouraged distributors to ensure access to buprenorphine for OUD. Federal legislators have proposed exempting buprenorphine from the Suspicious Order Reporting System.

Visit http://p2p.uky.edu/links for references and more

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Buprenorphine Barriers
Dispensing FAQ

When can the monoproduct be prescribed under KY regulations?

- Pregnancy
- Demonstrated hypersensitivity to naloxone
- Administered under supervision in a healthcare facility
- Transitioning from methadone to buprenorphine (limited to 1 week)
- Other specific patient circumstance determined and documented by prescriber (e.g., hepatic impairment)

When is multiple daily dosing allowed under KY regulations?

APRN: Not limited to once-daily dosing

Physician or PA: Once-daily dosing required unless:

- Pregnancy (BID)
- Dose less than 16 mg daily (BID)
- Cancer, hospice, or palliative care (BID or TID)
- Major surgery or significant physical trauma (BID or TID, up to 14 days)
- Other specific patient circumstance determined and documented by prescriber

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Dispensing FAQ

Can patients take additional opioids for acute pain while on buprenorphine?

Yes. The decision to prescribe opioids for pain should always be individualized and patient-centered. Dosing of buprenorphine may be adjusted to optimize pain management, but buprenorphine discontinuation for episodes of acute pain is typically not recommended. Patients and providers may have OUD treatment agreements with provisions for managing pain. Multimodal approaches, care coordination among prescribers, and quality patient counseling can increase safety and efficacy of pain management.

Can patients split buprenorphine-naloxone films?

The package insert indicates that the films "must be administered whole. Do not cut, chew, or swallow." However, an exploratory study found that splitting buprenorphine-naloxone 8-2 mg films in half yielded acceptable results in size and dose. Variation became unacceptable when splitting in quarters. Splitting is common in buprenorphine treatment, and adverse clinical outcomes have not been reported. Kentucky regulations do not prohibit off-label splitting of dosage forms.

References: 201 KAR 9:270; 201 KAR 20:65; Buresh M, et al. *J Gen Intern Med*. 2020;35(12):3635-3643; Drugs@FDA, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm; Reindel KL, et al. *Int J Pharm Compd*. 2019;23(3):258-263.

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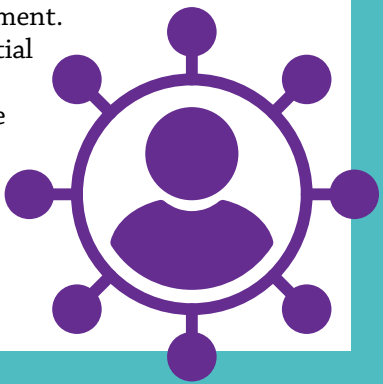
Buprenorphine Barriers
Coordinating Care

When is a consult required for buprenorphine prescribing under KY regulations?

If a patient is prescribed benzodiazepines, sedative hypnotics, stimulants, other opioids, or maintenance doses of buprenorphine greater than 16 mg, the **buprenorphine prescriber** must be or consult a specialist in addiction medicine or psychiatry prior to prescribing buprenorphine. Buprenorphine can be prescribed without consultation to "address an extraordinary and acute medical need not to exceed a combined period of 30 days."

What should I do if I can't reach a prescriber?

Weigh the risks and benefits of dispensing without the information that you are seeking. Place the patient at the center of your decision-making and avoid disruptions in treatment. Consider dispensing a partial fill or a one-time fill with a referral to an alternative source of care prior to refusing a prescription. Document attempts to contact the prescriber and communication with the patient.



Coordinating Care

What should I do if there are concerns about a prescriber's practice?

Questions about professional practice should be directed to the state board overseeing that profession. You may file a formal grievance or complaint about a practitioner through the appropriate board's website.

Board of Medical Licensure:
502-429-7150
https://kbml.ky.gov

Board of Nursing:
502-429-3300
https://kbn.ky.gov

Drug Enforcement and Professional Practices Branch:
502-564-7985

The Kentucky Drug Enforcement and Professional Practices Branch (DEPPB) enforces the Kentucky Controlled Substances Act. Investigators at DEPPB are registered pharmacists and sworn law enforcement officers. If you are concerned about a practitioner's prescribing of controlled substances, consider contacting DEPPB.

http://p2p.uky.edu/bridge

References: 201 KAR 9:270; 201 KAR 20:65

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