Comments on Behalf of the American Association of Psychiatric Pharmacists (AAPP)
Guidelines: https://nabp.pharmacy/buprenorphine-guidelines/

The Pharmacy Access to Resources and Medication for Opioid Use Disorder Guideline
A Joint Consensus Practice Guideline from the National Association of Boards of Pharmacy (NABP) and the National Community Pharmacists Association (NCPA)
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We thank the entire Steering Committee and Expert Panel for their efforts in addressing a complex, multi-faceted gap in the care of patients with opioid use disorders (OUD). Despite the varied sources of these barriers, pharmacists and pharmacies are uniquely positioned to affect change and advance the care being provided.

We stand with our community pharmacy colleagues who practice through these challenges on a daily basis. Although evidence suggests that stigma plays a role in pharmacy access to buprenorphine[1], we recognize this to be a small contributor to the intricate nature of the issue. Far more concern stems from unnecessary administrational and legal burden interfering with pharmacists' clinical decision making. We recognize that in absence of these barriers, the vast majority of our pharmacist colleagues stand ready and willing to help patients with OUD as originally committed to upon embracing the Oath of a Pharmacist. These guidelines lay the groundwork for overcoming these barriers and re-establishing pharmacists as the experts in determining the safety and appropriateness of the prescription orders they fulfill. At present, the written tone could be suggestive that pharmacist stigma is prompting many of the recommendations within. The Steering Committee may wish to explicitly acknowledge the existence of data surrounding stigma in our profession, while ensuring to separate this phenomenon from the language used within each of the recommendations.

Introduction and General Comments

1. Consider reorganizing the sections/recommendations to prioritize the action being recommended, followed by supporting statements thereafter.
2. Consider revising the second sentence of the introduction to clarify the indication of "methadone for OUD" as well as buprenorphine being "dispensed to patients" in community pharmacies.
3. Strongly consider including a recommendation about the appropriateness of filling medications for off-label purposes, which includes any buprenorphine formulation for a pain indication. This may warrant a review of the law changes that occurred with the Consolidated Appropriations Act of 2022, where language about specific formulations being used only for OUD was completely removed from old guidance.
4. Consider adding a section encouraging the patient-pharmacy relationship early on in the guidance. Building rapport with patients can be instrumental in reducing barriers and enhancing access to needed care.

Maintenance Pharmacotherapy with Buprenorphine

1. Consider an even stronger emphasis on the appropriateness of indefinite buprenorphine treatment in some cases.

2. Consider emphasizing the type of supply that is being encouraged to maintain. This may include a variety of different buprenorphine products and clarification that buccal and transdermal formulations should be accounted for. Consider strongly encouraging the creation of a par level to restock items where systems allow for this type of automation.
3. Consider adding guidance for pharmacists in the event a specific product is not in stock, but reasonable substitutions are available. Conversions between different products may be appropriate to ensure continuity of care, and guidance could help pharmacists identify appropriate alternatives.
4. Consider using language that generalizes "prescribers" and their "licensing board" in the second supporting recommendation given the numerous types of professions that may now prescribe buprenorphine. This concept is highlighted in the final supporting recommendation, and this should include mention of pharmacists as an additional legitimate prescriber type.
5. Consider providing data-driven examples to explain how "evidence of misuse" might present. Guidance would help pharmacists identify behavior without contributing to unnecessary concern.

Red Flags and Prescription Drug Monitoring Programs

1. Consider providing or referencing guidance on how to most appropriately interpret the data provided by the PDMP.
2. Strongly consider removing a specific value of dose increase that would warrant a concern. It may be more accurate to say that, similar to other medications, it would be concerning to note a significant dose change to a stable regimen.
3. Consider removing "multiple prescribers" as a red flag, as patients don't always have control over availability of consistent prescribers or may be transitioning between levels of care appropriately.
4. Consider rewording to clarify why it would be a red flag for a prescription to be issued more than 30 days ago or not be the most recent prescription, as it would still be a legal prescription. While the rationale portion provides some explanation, it seems unnecessary to identify an explicit timeframe for prescription appropriateness.
5. Consider removing the word "suspects" in favor of something less stigmatizing, such as "has reason to believe" or "assesses the potential for".
6. Consider providing examples for "medical complications" of buprenorphine pharmacotherapy to guide pharmacists in appropriate identification.
7. Consider adding telehealth expansion as another legitimate reason for possible larger distance between patient, provider, and pharmacy.
8. Strongly consider rewording the rationale behind the inclusion of "green flag" considerations or removing this supporting recommendation all together. At present, implying that medication refills provide evidence of "commitment to maintaining their recovery" is inappropriate and stigmatizing. Additionally, concurrent full agonist opioid prescriptions may be medically appropriate and would not inherently affect the stability of one's treatment. The concept of "green flags" may be best avoided.

Early Refills

1. Consider including an additional example of appropriate early refills in the instance a patient is entering a treatment facility.
2. Consider clearer guidance for pharmacists in states where laws may conflict with clinical judgement of appropriate early refills. For example, South Carolina does not allow for refilling controlled substances more than 48 hours early.[2]
3. Consider including guidance for responding to insurance company rejection for legitimate early refills, as well as the appropriateness of cash payment in these instances for continuity of care.

Providing Care to Persons Utilizing Telehealth

1. Strongly consider explicitly supporting the removal of policies that dictate the frequency of appointments or timeframe since being seen in-person by a provider. While a few states have laws that dictate such a relationship, the federal expansion of telehealth allowances no longer require an in-person assessment. Similarly, there is no universal requirement for appropriate frequency of follow-up and should not be a reason to limit prescription fills.
2. Consider rewording the final supporting recommendation to remove the concept of being "adherent to a stable plan of care," as this may be difficult to define or irrelevant. Pharmacists should continue to dispense buprenorphine to telehealth patients even if they change providers.

Buprenorphine Monotherapy

1. Strongly consider a more progressive stance on the appropriateness of buprenorphine monotherapy in a wide variety of clinical scenarios. It may be helpful to remove specific examples and generically state that buprenorphine monotherapy is appropriate in many clinical situations. In the absence of other red flags, a prescription for buprenorphine monotherapy should not raise concern.
2. It may be helpful in this section, or sooner, to clarify the various buprenorphine formulations that exclude naloxone, including transdermal and buccal formulations originally indicated for pain. This could include a supporting recommendation to ensure ordering caps take into account all formulations, not just those for OUD.
3. Consider explicitly recommending the removal of any ordering caps that include ratios of monotherapy to combination product limits. Such ratio caps may further impact the availability of buccal and transdermal formulations for pain as these products become more commonly utilized.

Recommendations to Protect Patient Safety

1. Strongly consider removing the suggestion to inquire about patient experiences with the medication, as this could be perceived as a patient interview that is being recommended against later on. This type of added counseling is not warranted for any other medication, and it may be more appropriate to suggest: "When appropriate or required by state law, pharmacists should discuss potential adverse effects of buprenorphine pharmacotherapy".

2. Consider expanding the recommendation for naloxone provision to include education on signs and symptoms of an opioid overdose in addition to traditional medication counseling for naloxone.
3. Consider emphasizing the importance of counseling a patient on proper administration of the various buprenorphine formulations to gain full benefit. This should include that swallowing a sublingual or buccal formulation will reduce efficacy and increase gastrointestinal side effects.
4. Consider including that buprenorphine for OUD is approved in patients 16 and older and there should be no additional scrutiny for adolescents who meet this criteria.

Care Coordination and Provider Communication

1. Consider adding to the second supporting recommendation that collaborative practice agreements could also lead to comprehensive medication management or prescribing authority in states where a DEA license is obtainable by pharmacists.

Stigma toward Persons with OUD

1. Consider including or referencing a guidance document on appropriate non-stigmatizing language to use when talking to or about patients with OUD[3].
2. Consider including guidance on the importance of fostering strong patient-pharmacy relationships to enhance care for patients with OUD. This could include suggestions on how to communicate with patients about the benefits of filling all prescriptions at a single pharmacy. While requiring this practice is unethical and should be abandoned, it would be inappropriate to completely avoid a discussion of how this may improve care and patient-pharmacy relationship.
3. Consider additional verbiage in the second supporting recommendation to clarify what is meant by a patient interview. Many recommendations involve a discussion with the patient prior to dispensing to clarify information, which could be perceived as an interview.

References

1. Light AE, Green TC, Freeman PR, Zadeh PS, Burns AL, Hill LG. Relationships between stigma, risk tolerance, and buprenorphine dispensing intentions among community-based pharmacists: results from a national sample. Substance Use & Addition Journal. 2024;45(2):211-221.
2. South Carolina Legislature. South Carolina Code of Regulations Chapter 61. Accessed May 13, 2024. Chapter 61-1 through 61-17.pdf (scstatehouse.gov) Accessed May 13, 2024.
3. National Institute on Drug Abuse. Words Matter Terms to Use and Avoid When Talking About Addiction.; 2021. Accessed May 13, 2024. Words Matter - Terms to Use and Avoid When Talking About Addiction | National Institute on Drug Abuse (NIDA) (nih.gov)