April 8, 2022

National Center for Injury Prevention and Control
Centers for Disease Control and Prevention
4770 Buford Highway NE
Mailstop S106-9
Atlanta, GA 30341

Attn: Docket No. CDC-2022-0024

On behalf of the American Association of Psychiatric Pharmacists (AAPP), we appreciate the opportunity to provide feedback on the Proposed 2022 CDC Clinical Practice Guideline for Prescribing Opioids. AAPP (presently transitioning from the name College of Psychiatric and Neurologic Pharmacists or CPNP) appreciates the revision of the 2016 Guidelines and the incorporation of the concerns of chronic pain stakeholders. We provide the following recommendations to inform the guidelines as they are finalized with the goal of not limiting clinicians in using their clinical judgement to provide the best care to patients.

AAPP is a professional association of nearly 3,000 members who envision a world where all individuals living with mental illness, including substance use disorders, receive safe, appropriate, and effective treatment. Psychiatric pharmacists graduate with a Doctor of Pharmacy degree, a required six to eight years of higher education, and have more training specific to medication use than any other health care professional. Psychiatric pharmacists, a specialty within clinical pharmacy, are primarily board certified and residency-trained mental health care practitioners who have specialized training in providing direct patient care and medication management for the complete range of psychiatric and substance use disorders. Psychiatric pharmacists work as treatment team members but also in decision-making and leadership roles in state and federal organizations, academia, and industry.

Clinical pharmacists, including psychiatric, pain management and palliative care pharmacists, can and do play a role in providing chronic pain management services. Psychiatric pharmacists are specifically trained to provide medication management, patient education and self-management, assessment and monitoring, and administration of a validated rating scale. Clinical pharmacists are a growing and essential part of the comprehensive treatment of pain and an integral part of the multidisciplinary team, utilizing collaborative relationships with providers.

Scope and audience

Pharmacists are regularly managing medication changes in the ambulatory care environment similar to advanced practice providers, especially in the primary care and mental health areas.

Therefore, AAPP requests the following addition on **page 16, lines 342-343**:

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clinicians (including physicians, nurse practitioners, physician assistants**,** ~~**and**~~ oral health practitioners**, and pharmacists** managing pain in outpatient settings

Opioid Tapering considerations

Recommendation #5. "For patients already receiving higher opioid dosages…"

AAPP believes this recommendation is not written clearly and seems to apply only to those on higher doses, presumably >50 MMEs. However, the content of this section relates to chronic opioid use that has been identified as potentially needing tapering. The wording of "higher dosages" can be confusing, should be interpreted based on individual patients, and easily may be taken out of context.

AAPP recommends the following change on **page 101, lines 2393-2400**:

"~~**For patients already receiving higher opioid dosages,**~~ ~~c~~Clinicians should carefully weigh benefits and risks and exercise care when reducing or continuing opioid dosage. If risks outweigh benefits of continued opioid therapy, clinicians should optimize other therapies and work closely with patients to gradually taper to lower dosages or, if warranted based on the individual clinical circumstances of the patient, to appropriately taper and discontinue opioids. Unless there are indications of a life-threatening issue, such as warning signs of impending overdose, e.g., confusion, sedation, or slurred speech, opioid therapy should not be discontinued abruptly, and clinicians should not abruptly or rapidly reduce opioid dosages**.** ~~**from higher dosages**~~ **"**

This section, **Implementation Considerations,** may result in misapplication by patients that tapering should never occur outside of a collaborative agreement between patient and provider. In clinical practice, this will result in the provider being unable to apply clinical judgment for best care. Clarity needs to be added so that this may occur.

AAPP recommends the following addition to the bullet point on **page 101, line 2407**:

- *"Patient agreement and interest in tapering is likely to be a key component of successful tapers.* ***However, patient agreement may not be achieved, and tapering may still be clinically indicated and necessary. In this case, clear documentation of the taper plan and communication with the patient should be completed****."*

AAPP recommends language be added related to the supporting roles of nursing and pharmacists in the ambulatory care setting to support clinicians. Specifically, AAPP recommends the additional wording to the bullet point on **page 101, line 2414**:

- "*Clinicians should follow up frequently (at least monthly) with patients engaging in opioid tapering.* ***Nursing and pharmacist resources are excellent resources to support the clinician and patient in the on-going taper process through phone contact, telehealth visits, or face to face visits.****"*

Tapering recommendations all assume long duration of chronic use. Chronic use is defined as >3 months. These recommendations may be misapplied to those who would benefit from a shorter taper duration and be successful.

AAPP recommends the following clarifying words be added to the bullet point on **page 102, line 2419-2421**:

- *"****For patients who have taken chronic opioids for several years****,* ~~***T***~~*tapers can be completed over several months to years depending on the opioid dosage and should be individualized based on patient goals and*

concerns. Longer durations of previous opioid therapy might require longer tapers ***while shorter durations of opioid use, (less than one year) may successful taper in a short period of time."***

AAPP recommends the following clarifying words be added to the bullet point on **page 102, line 2422-2424**:

- *"Tapers of 10% per month or slower are likely to be better tolerated than more rapid tapers, particularly when patients have been taking opioids for longer durations (e.g., for a year or longer).* ***For those taking chronic opioids for shorter durations, a faster tapering rate and speed may be appropriate."***

Patients unable to taper may be a sign to readdress OUD.

AAPP recommends the following clarifying words be added to the bullet point on **page 102, line 2445-2447**:

- "*Clinicians should closely monitor patients who are unable to taper and who continue on high- dose or otherwise high-risk opioid regimens (e.g., opioids prescribed concurrently with benzodiazepines) and should work with patients to mitigate overdose risk (e.g., by providing overdose education and naloxone—see Recommendation 8.* ***Signs of opioid misuse during a taper reflects the need to re-evaluate OUD (see Recommendation 12)."***

Naloxone

Although access to naloxone has increased, barriers still exist for patients to obtain naloxone related to cost considerations. Insurers should be encouraged to increase access by eliminating cost barriers.

AAPP recommends adding a bulleted statement **on page 103, between lines 2458 and 2459; and page 125, between lines 3036 -3037:**

- ***"To improve access and reduce overdose associated risks, health insurers and health systems should improve coverage, including the consideration of no-copays for naloxone to increase access to patients both while tapering opioids and those identified as high risk for overdose."***

Communication with the care team

Buprenorphine and full opioid agonists:

AAPP recommends adding clarification on **page 113, between lines 2713-2714**:

"The use of buprenorphine and full opioid agonists may result in communication confusion between the patient and members of the care team. Pharmacists are trained to monitor for medication indication, dose, drug-drug interactions, and patient diversion. To ensure that patients receive medications as prescribed, clinicians should routinely document indication and consider potential drug-drug interactions such as co-prescribing buprenorphine and opioids or opioids and benzodiazepines/CNS depressants. In these cases, clinicians should communicate with all members of the care team such as the pharmacist and nurse."

AAPP recommends the addition of the following bullet point on **page 115, line 2746:**

- ***"Pharmacists can play an important role as part of treatment team but are facing extensive barriers in dispensing opioids, especially buprenorphine. Pharmacist face barriers such as wholesale quotas and regulatory dispensing requirements, which may prevent them from dispensing medications in a timely fashion. Clinicians should work to develop an easy system for timely communication with local***

***pharmacists to ensure that medication is available for patients. Clinicians should encourage pharmacies to routinely stock commonly prescribed opioids including buprenorphine and inquire about barriers.*"**

Medication related references:

Laxative reference:
The guidelines incorrectly identify senna as a cathartic laxative.

AAPP recommends the following change on **page 73, line 1696-1697**:

"A ~~cathartic~~ **stimulant laxative** (e.g., senna) with or without a stool softener ~~**or a laxative**~~ might be needed if opioids are used for more than a few days **to ensure regular bowel movements**. **Stool softeners or fiber laxatives without another laxative should be avoided.**"

AAPP recommends the following change on **page 88, line 2060-2061:**

"A ~~cathartic~~ **stimulant laxative** (e.g., senna) with or without a stool softener or **another** ~~**a**~~ laxative **is almost always necessary for patients taking opioids chronically to ensure regular bowel movements** ~~**might be needed**~~**. Stool softeners or fiber laxatives without another laxative should be avoided**."

ER/LA guidance:
As worded, the dosing guidance may be taken as a hard number and this definition is not evidence-based.

AAPP recommends the following change on **page 91, line 2148-2151 and again on page 94, lines 2230-2233:**

- "*ER/LA opioids should be reserved for severe, continuous pain. Some ER/LA opioids should be considered only for patients who have received certain dosages of opioids (e.g., 60 mg daily of oral morphine, 30 mg daily of oral oxycodone, or equianalgesic dosages of other opioids) of immediate-release opioids daily for at least 1 week.* ***However, lower doses may also be appropriate in some situations when converting to an equianalgesic dose of an ER/LA opioid.****"*

Fentanyl patches:
The guidelines do not include the dangers and risks of cutting fentanyl as described by Institute for Safe Medication Practices.[1,2]

AAPP recommends describing the dangers and risk and including references on **page 94, lines 2219-2224.**

Thank you again for the opportunity to comment on this important patient care issue. If you have any questions or require any additional information, please do not hesitate to contact me or our Health Policy Consultant, Laura Hanen at lahanen@venable.com.

Sincerely,

Brenda K. Schimenti
Executive Director

[1] https://www.pharmacytoday.org/article/S1042-0991(15)31507-3/pdf
[2] https://www.ismp.org/sites/default/files/attachments/2018-11/fentanyl1-13.pdf