



January 13, 2016

Veronica Kennedy

Acting Executive Secretary, Centers for Disease Control and Prevention
National Center for Injury Prevention and Control, Centers for Disease Control and Prevention,
4770 Buford Highway NE., Mailstop F-63,
Atlanta, GA 30341

Re: Draft Guideline for the Use of Opioids for Chronic Pain (Docket No. CDC-2015-0112)

Dear Acting Executive Secretary Kennedy:

The American College of Physicians (ACP) commends the Centers for Disease Control and Prevention (CDC) for developing the ***Draft Guideline for the Use of Opioids for Chronic Pain***, and offering this opportunity for public comment. The ACP is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 143,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness

This guideline development effort is both timely and necessary to help effectively address the increasingly clear public health problem of inappropriate opioid use and its related adverse consequences. The guideline:

“provides recommendations for primary care providers who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care” with the intended purpose “to improve communication between providers and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy, including abuse, dependence, overdose, and death.”

The College particularly commends the CDC for focusing the guideline on primary care healthcare professionals, who serve as the first contact for most patients suffering from pain-related conditions, and who, according to a recent study¹, are the largest prescribers of schedule II opioid medications. We believe that the targeting of appropriate changes in opioid prescribing practices and chronic pain management within primary care, based on the best

¹ Chen JH, Humphreys K, Shah NH and Lambke A. Distribution of opioids by different types of Medicare prescribers. *JAMA Intern Med*. Published on line December 14, 2015. Available at <http://archinte.jamanetwork.com/article.aspx?articleid=2474400>



available clinical evidence, is a requisite component of any national effort to effectively address this public health problem.

The College has divided its comments into those that are overarching and address the general Guideline document, and those specifically linked to a Guideline recommendation.

Overarching, General Comments:

- **The Guideline as a Set of Recommendations and not Prescriptive Standards.** The guideline states that it “offers recommendations rather than prescriptive standards; providers should consider the circumstances and unique needs of each patient.” We strongly agree with this position --- the uniqueness of each patient’s clinical situation and circumstances is a paramount consideration in the effective delivery of care. We believe this position requires increased elaboration and emphasis both in the preface (Background section) where it is only reflected in a one-sentence statement at the end of the section, and throughout the recommendations. We are concerned that without increased emphasis of this position, there is undue risk of policy makers, institutions, and payers using aspects of the Guideline in a manner that will inappropriately decrease access to opioid medications for individuals for whom they serve as the most effective means of addressing pain and increasing functionality. The importance of highlighting this “recommendation, not prescriptive standard” position is further supported by the relatively weak evidentiary basis for many of the recommendations. While the recommendations are based on the best evidence available, as clearly stated in the Guideline document, the “clinical scientific evidence informing the recommendations is low in quality.”
- **The Need to Place the Guideline within a Broader Context** The College encourages CDC to add a discussion within the Guideline document reflecting how these recommendations align with the other federal efforts (e.g. Office of National Drug Control Policy; initiatives of the National Institute on Drug Abuse and the Substance Abuse and Mental Health Administration ; and the recently released initiative through the Department of Health and Human Services) to address the problems related to opioid medication use and misuse. The effectiveness of the CDC Guidelines depends upon the success of these other federal efforts --- to promote relevant education, reduce barriers to the full array of available pain treatments, increase monitoring efforts regarding opioid use, promote further necessary research, reduce the effects of stigma



on receiving appropriate care, and effectively reduce illicit diversion --- and these parallel efforts should be reflected within the Guideline document.

Comments on Specific Recommendations

1. Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Providers should only consider adding opioid therapy if expected benefits for both pain and function are anticipated to outweigh risks to the patient (recommendation category: A, evidence type 3).

ACP policy supports the “consideration by physicians of the full array of treatments available for the effective treatment and management of pain.”² We are aware that the literature reflects,³⁴ as a result of cultural trends, patient demands, and the time restraints of a typical patient visit, the observation that many physicians tend to respond too quickly to patient pain reports with controlled substances, particularly opioid medications. The College encourages physicians to consider the broad set of therapies available for the effective treatment and management of pain. This “toolkit” starts with strong patient–physician relationships and supportive systems of care, and further can include nonaddictive medications (such as acetaminophen, nonsteroidal anti-inflammatory drugs, and antidepressants); controlled medications; physical therapy; psychotherapy and counseling; mind–body approaches (such as relaxation therapy, biofeedback, hypnosis, and yoga); and various alternative therapies (such as acupuncture).

As a result of our policy, we are supportive of the general position reflected within the recommendation, but are concerned that the wording “Providers should only consider adding opioid therapy” as reflecting too rigid of a position. As currently stated, the Guideline does not adequately recognize those patients whose particular clinical situations and circumstances would make the use of opioid therapy (potentially in combination with nonpharmacologic therapy and nonopioid pharmacologic therapy), as the most appropriate first-line intervention to alleviate pain and improve function. For example, this is often the case for patients who have completed their active oncological treatment, but are still experiencing chronic moderate-to-

² Kirschner N, Ginsburg J, Snyder Sulmasy L. Prescription drug abuse: Executive summary of a policy position paper from the American College of Physicians. *Ann Intern Med.* 2014;160(3):198-200. Available at <http://annals.org/article.aspx?articleid=1788221>

³ Lembke A. Why doctors prescribe opioids to known opioid abusers. *N Engl J Med.* 2012; 367:1580-1581

⁴ Ballantyne JC, Sullivan MD. Why doctors prescribe opioids to known opioid abusers [Letter]. *N Engl J Med.* 2013; 368:484-5.



severe cancer-related pain. Thus, we recommend modification of the recommendation's wording to address this concern.

The College also suggests that the Guideline document call for payment policy changes both within the public and private sector that will facilitate access to nonpharmacological therapies.

2. Before starting opioid therapy for chronic pain, providers should establish treatment goals with all patients, including realistic goals for pain and function. Providers should not initiate opioid therapy without consideration of how therapy will be discontinued if unsuccessful. Providers should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety (recommendation category: A, evidence type: 4).

The College generally supports this recommendation, but would suggest that the following section of the recommendation "Providers should continue opioid therapy only if there is clinically meaningful improvement in pain and function" be modified to recognize, as stated in the discussion, that there are some limited clinical circumstances under which reductions in pain without improvement in function might be an appropriate goal (e.g., diseases typically associated with progressive functional impairment or catastrophic injuries such as spinal cord trauma).

3. Before starting and periodically during opioid therapy, providers should discuss with patients known risks and realistic benefits of opioid therapy and patient and provider responsibilities for managing therapy (recommendation category: A, evidence type: 3).

The College supports this recommendation, but suggests the word "discuss" be changed to "inform" or "educate" to allow for approaches other than first-person conversations to communicate the necessary information. For example, one approach could be the use of a decision support film that addresses the issues indicated within the recommendation, followed by an opportunity to ask questions.

Opioid Selection, Dosage, Duration, Follow-Up, and Discontinuation

4. When starting opioid therapy for chronic pain, providers should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids (recommendation category: A, evidence type: 4).



The College supports this recommendation, but suggests some further elaboration in the discussion section regarding how the term “familiar” is defined in regard to the prescribing of methodone and transdermal fentanyl patches.

5. When opioids are started, providers should prescribe the lowest effective dosage. Providers should use caution when prescribing opioids at any dosage, should implement additional precautions when increasing dosage to ≥ 50 morphine milligram equivalents (MME)/day, and should generally avoid increasing dosage to ≥ 90 MME/ day (recommendation category: A, evidence type: 3).

The College fully supports the first section of recommendation that “providers should prescribe the lowest effective dosage.” While not apparently the intent, we are concerned that the remainder of the recommendation (e.g. morphine milligram equivalent maximum dosage of 90 MME) can too easily be misused (too rigidly applied) by payers and others in a manner that will decrease access to appropriate and effective pain medication for specific patients. ACP favors establishment of evidence-based, nonbinding guidelines regarding recommended dosage that a patient taking controlled substance medications may receive.”⁵ Physicians must be responsive to the specific and unique needs of their patients. They must be able to adjust medication dosages according to individual needs that may vary over time and are not the same for all patients. Consequently, ACP opposes arbitrary maximum dosages by payers and health plans. These guidelines are instructive, but like any guidelines, they should not be rigidly applied and there must be some flexibility to allow adjustments in determining dosages reflecting physician judgment. Thus, we suggest at least highlighting that the recommendation only reflects an instructive guideline, and the actual dosages used should be based on the patient’s clinical response.

6. Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, providers should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three or fewer days usually will be sufficient for most nontraumatic pain not related to major surgery, (recommendation category: A, evidence type: 4).

⁵ Kirschner N, Ginsburg J, Snyder Sulmasy L. Prescription drug abuse: Executive summary of a policy position paper from the American College of Physicians. *Ann Intern Med.* 2014;160(3):198-200. Available at <http://annals.org/article.aspx?articleid=1788221>



The College supports this recommendation with the following modification to the last sentence of the recommendation--- “Three or fewer days usually will be sufficient for most nontraumatic pain not related to major surgery, with re-evaluation of the need for additional opioids at the conclusion of the three days.” The 3-day limit without the modification can too easily be rigidly and inappropriately applied by payers.

7. Providers should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Providers should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, providers should work with patients to reduce opioid dosage and to discontinue opioids (recommendation category: A, evidence type: 4).

The College supports this recommendation that highlights the importance of continued monitoring for benefits and harm of patients receiving opioid therapy.

Assessing Risk and Addressing Harms of Opioid Use

8. Before starting and periodically during continuation of opioid therapy, providers should evaluate risk factors for opioid-related harms. Providers should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, or higher opioid dosages (≥ 50 MME), are present (recommendation category: A, evidence type: 4).

The College supports this recommendation. While the discussion section provides some guidance regarding risk assessment, we agree with the findings in the evidence review that concludes that primary care physicians are generally not well equipped to assess risk. Thus, we would recommend some increased elaboration on risk assessment approaches within the discussion section, and also an explicit statement in the discussion that primary care physicians consider referral to specialists in pain management for those patients whom they consider to be at high risk for opioid harm.

The College, as a member of the American Medical Association (AMA) Task Force to Reduce Opioid Abuse strongly supports expanded access to naloxone both in the community and through co-prescribing. (<http://www.ama-assn.org/ama/pub/advocacy/topics/preventing-opioid-abuse/opioid-abuse-task-force.page>)



9. Providers should review the patient’s history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving high opioid dosages or dangerous combinations that put him or her at high risk for overdose. Providers should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months (recommendation category: A, evidence type: 4).

The College supports this recommendation. Furthermore, the College appreciates recognition in the discussion of the problems related to our current system of state-based PDMPs (e.g. unavailability of prescription data obtained in border-states). As a result of this problem, the College has called for the establishment of a national Prescription Drug Monitoring Program.⁶ The College further commends the CDC for including within the discussion section guidance related to how to properly and effectively use the information obtained from this source; we were particularly pleased to see the guidance that healthcare professionals “should not dismiss patients from their practice on the basis of PDMP information. Doing so can adversely affect patient safety, could represent patient abandonment, and could result in missed opportunities to provide potentially lifesaving information.”

PDMP monitoring can be quite time consuming, and efforts to minimize this administrative burden should be encouraged --- this can include encouraging laws that allow provider delegation. Mandated excessive frequency of checking the PDMP also serves as a burden--- more research is needed to determine the optimal intervention points to effectively address opioid harm.

10. When prescribing opioids for chronic pain, providers should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs (recommendation category: B, evidence type: 4).

ACP supports this recommendation that promotes the use of urine drug testing as part of a treatment plan for patients receiving opioid therapy for chronic pain. We further appreciate the guidance provided within the discussion section regarding on how to employ this approach, use the information provided, its limitations and how various factors can affect its validity. Again, we commend CDC for including the caveat that healthcare professionals should not dismiss patients from their practice based on this information. An issue not explicitly discussed within

⁶ Ibid



the guidance concerns the non-adherent patient --- we suggest some guidance addressing this issue be included within the discussion section.

Drug testing costs for patients can be high, since drug tests may be considered medically unnecessary and thus not covered by insurance.⁷ We suggest that the Guideline document call for payers to remove this barrier, and for healthcare professionals to consider this financial issue in treatment plan development. Furthermore, more research is needed to make the most effective use of this monitoring approach.

11. Providers should avoid prescribing opioid pain medication for patients receiving benzodiazepines whenever possible (recommendation category: A, evidence type: 3).

The College generally supports this recommendation and again appreciates the additional guidance included within the discussion section regarding tapering off strategy. We also suggest the addition of an explicit statement in the discussion that primary care physicians consider referral to specialists in pain management for those patients currently on both benzodiazepines and opioids, or for the limited set of patients who might benefit from such co-prescribing.

12. Providers should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder (recommendation category: A, evidence type: 3).

The College conceptually is in full support of this recommendation, but believes, as worded, it minimizes the substantial practical problems linked to its implementation. We believe that the primary care setting serves as the point of first healthcare contact for most individuals with opioid use disorder and suggest that the Guideline elaborate in greater detail approaches for these healthcare professionals to diagnose its presence. Improved ability by primary care professionals to diagnose this problem is a realistic goal. Furthermore, as briefly mentioned within the discussion, obtaining appropriate treatment for these patients is often problematic as a result of the limited expertise that many primary care professionals have in directly treating this disorder, the lack of skilled specialists and facilities within the community in many geographic areas to provide necessary treatment, cost concerns related to limited coverage for these services offered through most public and private payers, and the role that stigma plays both in patients seeking treatment and health professionals providing it. Thus, while many of

⁷ Cheves J. Urine tests required by new drug law can cost patients hundreds of dollars. Kentucky.com. 27 September 2012. Available at www.kentucky.com/2012/09/27/2352733/drug-tests-required-by-new-law.html



these issues are briefly mentioned within the discussion, we suggest that the wording within the actual recommendation reflect the presence of these barriers.

The College appreciates this opportunity to comment on the proposed *Draft Guideline for the Use of Opioids for Chronic Pain*. Please contact Neil Kirschner Ph.D. at 202 261-4535 or nkirschner @acponline.org if you have any questions regarding the comments or would like to discuss them in greater detail.

Respectfully,

A handwritten signature in black ink, appearing to read "Wayne Riley", with a stylized flourish at the end.

Wayne Riley, MD, MPH, MBA, MACP
President