April 1, 2022

Rochelle Walensky, MD, MPH
Director
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30333
Attn: Docket No. CDC-2022-0024

Submitted electronically at http://www.regulations.gov

Re: Proposed 2022 CDC Clinical Practice Guideline for Prescribing Opioids

Dear Director Walensky:

On behalf of the American Society of Regional Anesthesia and Pain Medicine (ASRA Pain Medicine), thank you for the opportunity to submit comments to the Centers for Disease Control and Prevention (CDC) in response to the proposed *CDC Clinical Practice Guideline for Prescribing Opioids – United States, 2022* (2022 Guideline).

ASRA Pain Medicine is a professional organization of more than 5,000 physicians and other healthcare providers dedicated to the specialties of acute and chronic pain medicine. Our vision is to reduce the global burden of pain. We believe that properly treating pain in the acute stage – including through interventional procedures like nerve blocks and epidural steroid injections – significantly reduces the burden of chronic pain. This is important because chronic pain affects an estimated 50 million adults in the United States, according to data from the CDC.[1] These are individuals who experience limited function, which can affect their ability to lead normal lives, work in productive and meaningful jobs, and connect with others. In other words, chronic pain affects just about every aspect of the lives of patients and society. To be able to fully address this issue would have a profound impact on our entire country – and the world.

Unfortunately, treatment of pain can be complex, and responses to treatments may vary widely across patients. Furthermore, use of opioid therapies – which have been among the most widely used treatment options for pain management – has too often resulted in tragic consequences, including addiction, opioid misuse, overdose, and/or death. As such, we recognize CDC's interest in

[1] Dahlhamer J, Lucas J, Zelaya C, et al. Prevalence of chronic pain and high-impact chronic pain among adults – United States, 2016. *Morbidity and Mortality Weekly Report.* 2018;67:1001-1006. DOI: http://dx.doi.org/10.15585/mmwr.mm6736a2.

promulgating clinical practice guidelines to support evidence-based decision-making in the prescription of opioid medications for the treatment of acute and chronic pain. However, there is broad agreement that the *2016 CDC Clinical Practice Guideline for Prescribing Opioids* (2016 Guideline) was too focused on curbing opioid utilization – with less room for personalized treatment plans, which incorporate patients' needs or circumstances – and unintentionally resulted in forced harmful dosing limits and decreased patient access to medically necessary opioid treatments.

ASRA Pain Medicine is therefore pleased to see the proposed 2022 revision to the 2016 Guideline. The proposed 2022 Guideline is more balanced, flexible, and patient-centered than its 2016 counterpart and leaves room for physician evaluation and management, rather than having physicians serve a policing function that limits patient care. We particularly appreciate the CDC's clarification and emphasis that these *recommendations* are voluntary and intended to support individualized, person-centric care, and are not meant to serve as mandatory guidelines. We also appreciate the CDC's recognition of the various considerations that physicians and other practitioners evaluate prior to the prescribing of opioids – for example, striving to ensure that patients' understand how opioid effectiveness will be evaluated, establishing voluntary treatment goals, and determining an "exit strategy" to avoid patient harm from forced opioid tapering or upper limit dose restrictions. Likewise, we support the strong messaging in opposition to rapid tapering or abrupt discontinuation of opioids, which should be discouraged, particularly when alternative treatment plans are readily available.

At the same time, we have concerns that there are significant gaps in the evidence and recommendations included in the proposed 2022 Guideline, and we respectfully offer the following recommendations for your consideration in its revision:

- ***Similar to the extensive sections on noninvasive pain treatments, include a critical discussion on the role of different interventional pain procedures for chronic AND acute pain (Recommendations 1 and 2)***
- ***Support transitions to buprenorphine for patients unable to taper (Recommendation 5)***
- ***Clearly articulate the need to prescribe naloxone for patients taking both opioids and benzodiazepines (Recommendation 11)***
- ***Rather than recommend that all clinicians obtain a waiver to prescribe buprenorphine, address the harms of the existing waiver requirements and the need to expand access to buprenorphine to facilitate treatment of opioid use disorder (Recommendations 5 and 12)***
- ***Provide greater nuance with respect to dismissal of patients from physician practices, including acknowledging circumstances where such dismissal may be appropriate (Recommendations 5, 9, 10, and 12)***

We provide more detail on these recommendations below.

Similar to the extensive sections on noninvasive pain treatments, include a critical discussion on the role of different interventional pain procedures for chronic AND acute pain (Recommendations 1 and 2)

The proposed 2022 Guideline notes that nonopioid therapies are effective for many common types of acute pain (Recommendation 1) and preferred for subacute and chronic pain (Recommendation 2). However, there is no discussion of interventional approaches for managing acute pain under Recommendation 1 and only a very brief discussion of interventional pain procedures, which are

lumped together (despite differences in application and mechanism of action), under Recommendation 2. We believe this represents a glaring oversight and missed opportunity to promote an effective, evidence-based alternative to opioid therapies in the management of acute, subacute, and chronic pain.

Numerous studies have demonstrated the effectiveness of interventions such as epidural steroid injections, peripheral nerve blocks, and catheters for the treatment of acute pain, including for patients discharged from inpatient facilities. (See, for example, Boin et al., 2021; Cardwell et al., 2021; Coopey et al., 2013; Guay, Johnson et al., 2017; Guay, Parker et al., 2017; Johnson et al., 2020; Joshi et al., 2016; Paul et al, 2010; Richman et al., 2006; Samineni et al., 2021; and Spijker-Huiges A, et al., 2014) And contrary to the proposed Guideline, which states that "evidence is limited" for many interventional procedures such as epidural steroid injections, nerve ablation procedures, and neurostimulation procedures for subacute and chronic pain, there is an expanse of research that demonstrates the safety, effectiveness, and cost-effectiveness of such interventions in applicable clinical scenarios, as well as their success in reducing opioid usage. (See, for example, Cohen et al., 2008; Cohen et al., 2012; De Andres et al., 2017; Ghahreman et al., 2010; Knezevic et al., 2021; Knotkova et al., 2021; Loh et al., 2019; Mekhail et al., 2020; Patel et al., 2012; Sdrulla et al., 2018; Star et al., 2020; and Yang et al., 2021.) The discussion of the supporting rationale under Recommendation 2 is additionally problematic as it paints a lopsided picture of epidural injections, noting that "rare, serious adverse events have been reported" but failing to report on the more commonly realized benefits.

We therefore recommend that the 2022 Guideline be updated to include a robust discussion on the role of interventional pain procedures as effective opioid-sparing therapies for the management of pain, including for acute, subacute, and chronic pain. This discussion should provide a balanced assessment of the evidence for the wide range of procedures that may be performed by interventional pain specialists, as well as information on when such treatments are medically necessary and appropriate and the need for insurers and health systems to ensure access under such conditions.

Support transitions to buprenorphine for patients unable to taper (Recommendation 5)

Recommendation 5 specifies that, for patients already receiving higher opioid dosages, clinicians should carefully weigh benefits and risks when reducing or continuing opioid dosages. Later in the supporting rationale for this recommendation, the proposed 2022 Guideline discusses the benefits of transitioning buprenorphine for patients for whom the benefits do outweigh the risks, but who are unable to taper. We believe this is an important strategy in mitigating the risks of opioid usage, and that patients and practitioners are not well-served by embedding this discussion in the middle of the Guideline, rather than highlighting the benefits of transitions to buprenorphine within the recommendation itself. Relative to schedule 2 opioids, for example, use of buprenorphine could significantly reduce the effects of withdrawal and the risk of overdose death (Kohan et al., 2021), and buprenorphine is also much easier to prescribe and manage in outpatient settings. As such, we recommend that Recommendation 5 be expanded to highlight the benefits of transition to buprenorphine for patients unable to taper.

Clearly articulate the need to prescribe naloxone for patients taking both opioids and benzodiazepines (Recommendation 11)

ASRA Pain Medicine appreciates that the proposed 2022 Guideline includes guidance throughout the document recommending the prescription of naloxone for patients taking both opioids and benzodiazepines, including in the implementation considerations for Recommendation 8. However, in Recommendation 11, which specifically addresses concurrent use of these medications, there is no guidance to prescribe naloxone in either the recommendation itself or the implementation considerations. We believe this is an inadvertent oversight that should be corrected. Both Recommendation 11 and the overall 2022 Guideline would be strengthened by clearly articulating a recommendation to prescribe naloxone for patients taking both opioids and benzodiazepines.

Rather than recommend that all clinicians obtain a waiver to prescribe buprenorphine, address the harms of the existing waiver requirements and the need to expand access to buprenorphine to facilitate treatment of opioid use disorder (Recommendations 5 and 12)

The proposed 2022 Guideline notes that prescription of buprenorphine for treatment of opioid use disorder requires clinicians to have a waiver from the Substance Abuse and Mental Health Services Administration (SAMHSA), and states that "all clinicians … should obtain a waiver to prescribe buprenorphine." ASRA Pain Medicine objects to this statement, which is overly burdensome, impractical, and unnecessary. Indeed, we believe that the waiver requirement creates significant barriers for physicians to prescribe and for patients to access buprenorphine, resulting in unnecessary morbidity and mortality from opioid use disorder. A better policy solution would be to expand access to buprenorphine by eliminating the waiver requirement and expanding coverage to include all buprenorphine products. While we recognize that elimination of the waiver requirement would require changes to statute, we believe the Guideline would benefit from a more robust discussion of the harms of the waiver requirement and the need to eliminate the requirement to increase access to buprenorphine. A recommendation for insurers to expand access to buprenorphine treatments would also support care for opioid use disorder.

Provide greater nuance with respect to dismissal of patients from physician practices, including acknowledging circumstances where such dismissal may be appropriate (Recommendations 5, 9, 10 and 12)

The proposed 2022 Guideline reiterates that clinicians should not dismiss their patients from their practice because of opioid use disorder or related indicators such as a failed toxicology test or evidence of improper opioid usage presenting in a prescription drug monitoring program (PDMP). ASRA Pain Management appreciates the message that practitioners have obligations to their patients, including to support patient safety, and that dismissal from practices may constitute patient abandonment. While we agree that clinicians should not dismiss patients from their practice solely because of opioid use disorder or related indicators, we are concerned that the draft Guideline is too proscriptive on this matter and does not sufficiently acknowledge the flexibility that practitioners require to make treatment and patient management decisions. Unfortunately, there are too many cases when patients may engage in noncompliant, irresponsible, disruptive, or even harmful or threating behaviors to the treatment team that undermine a physician's ability to successfully manage the patient's care in safe and nonthreatening manner. In such cases, physicians should have the discretion to take actions that may ultimately result in dismissal of patients from their practice.

As such, additional consideration of such circumstances and greater nuance with respect to physicians' needs and options is warranted in the 2022 Guideline.

***

ASRA Pain Medicine appreciates your consideration of our comments on the proposed 2022 Guideline and would be pleased to serve as an ongoing resource as the CDC continues to consider the role of opioid and non-opioid therapies in the management of pain. If you have any questions about our comments, please do not hesitate to contact Angela Stengel at 412-471-2718 or astengel@asra.com.

Sincerely,

Samer Narouze, MD, PhD
ASRA Pain Medicine President

References

Boin MA, Mehta D, Dankert J, Umeh UO, Zuckerman JD, Virk MS. Anesthesia in total shoulder arthroplasty: A systematic review and meta-analysis. *JBJS Rev* 2021; 9: e21.00115.
Cardwell TW, Zabala V, Mineo J, Ochner CN. The effects of perioperative peripheral nerve blocks on peri- and postoperative opioid use and pain management. *Am Surg.* 2021 Jun 23:31348211023395. doi: 10.1177/00031348211023395. Epub ahead of print. PMID: 34162251.

Coopey SB, Specht MC, Warren L, Smith BL, Winograd JM, Fleischmann K. Use of preoperative paravertebral block decreases length of stay in patients undergoing mastectomy plus immediate reconstruction. *Ann Surg Oncol* 2013;20(4):1282-6. doi: 10.1245/s10434-012-2678-7. Epub 2012 Oct 14. PMID: 23064793.

Cohen SP, Hurley RW, Buckenmaier CC, Kurihara C, Morlando B, Dragovich A. Randomized placebo-controlled study evaluating lateral branch radiofrequency denervation for sacroiliac joint pain. *The Journal of the American Society of Anesthesiologists.* 2008 Aug 1;109(2):279-88. doi: 10.1097/ALN.0b013e31817f4c7c.

Cohen SP, White RL, Kurihara C, Larkin TM, Chang A, Griffith SR, Gilligan C, Larkin R, Morlando B, Pasquina PF, Yaksh TL. Epidural steroids, etanercept, or saline in subacute sciatica: a multicenter, randomized trial. *Annals of Internal Medicine*. 2012;156(8):551-9. doi: 10.7326/0003-4819-156-8-201204170-00002.

De Andres, J., Monsalve-Dolz, V., Fabregat-Cid, G., Villanueva-Perez, V., Harutyunyan, A., Asensio-Samper, J.M. and Sanchis-Lopez, N., 2017. Prospective, randomized blind effect-on-outcome study of

conventional vs high-frequency spinal cord stimulation in patients with pain and disability due to failed back surgery syndrome. *Pain Medicine*, *18*(12), pp.2401-2421. doi: 10.1093/pm/pnx241.

Ghahreman A, Ferch R, Bogduk N. The efficacy of transforaminal injection of steroids for the treatment of lumbar radicular pain. *Pain Medicine.* 2010 Aug 1;11(8):1149-68. doi: 10.1111/j.1526-4637.2010.00908.x.

Guay J, Johnson RL, Kopp S. Nerve blocks or no nerve blocks for pain control after elective hip replacement (arthroplasty) surgery in adults. *Cochrane Database Syst Rev* 2017; 10: CD011608.

Guay J, Parker MJ, Griffiths R, Kopp S. Peripheral nerve blocks for hip fractures. *Cochrane Database Syst Rev.* 2017 May 11;5(5):CD001159. doi: 10.1002/14651858.CD001159.pub2. Update in: *Cochrane Database Syst Rev.* 2020;11:CD001159. PMID: 28494088; PMCID: PMC6481480.

Johnson P, Hustedt J, Matiski T, Childers R, Lederman E. Improvement in Postoperative Pain Control and Length of Stay With Peripheral Nerve Block Prior to Distal Radius Repair. *Orthopedics* 2020;43(6):e549-e552. doi: 10.3928/01477447-20200721-14. Epub 2020 Aug 6. PMID: 32745216.

Joshi G, Gandhi K, Shah N, Gadsden J, Corman SL. Peripheral nerve blocks in the management of postoperative pain: challenges and opportunities. *J Clin Anesth*. 2016;35:524-529. doi: 10.1016/j.jclinane.2016.08.041. Epub 2016 Oct 20. PMID: 27871587.

Kohan L, Potru S, Barreveld AM, Sprintz M, Lane O, Aryal A, Emerick T, Dopp A, Chhay S, Viscusi E. Buprenorphine management in the perioperative period: educational review and recommendations from a multisociety expert panel. *Reg Anesth Pain Med. 2021;46(10):840-859.* doi: 10.1136/rapm-2021-103007.Epub 2021 Aug 12.

Knezevic NN, Candido KD, Vlaeyen JWS, Van Zundert J, Cohen SP. Low back pain. *Lancet*. 2021;398(10294):78-92. doi: 10.1016/S0140-6736(21)00733-9. Epub 2021 Jun 8. PMID: 34115979.

Knotkova H, Hamani C, Sivanesan E, Le Beuffe MFE, Moon JY, Cohen SP, Huntoon MA. Neuromodulation for chronic pain. *Lancet*. 2021;397(10289):2111-2124. doi: 10.1016/S0140-6736(21)00794-7. PMID: 34062145.

Loh E, Reid JN, Alibrahim F, Welk B. Retrospective cohort study of healthcare utilization and opioid use following radiofrequency ablation for chronic axial spine pain in Ontario, Canada. *Reg Anesth Pain Med.* 2019;44(3):398-405. doi: 10.1136/rapm-2018-100058. Epub 2019 Jan 23. PMID: 30679335.

Mekhail N, Levy RM, Deer TR, Kapural L, Li S, Amirdelfan K, Hunter CW, Rosen SM, Costandi SJ, Falowski SM, Burgher AH. Long-term safety and efficacy of closed-loop spinal cord stimulation to treat chronic back and leg pain (Evoke): a double-blind, randomised, controlled trial. *The Lancet Neurology*. 2020;19(2):123-34. doi: 10.1016/S1474-4422(19)30414-4.

Patel N, Gross A, Brown L, Gekht G. A randomized, placebo-controlled study to assess the efficacy of lateral branch neurotomy for chronic sacroiliac joint pain. *Pain Medicine*. 2012 Mar 1;13(3):383-98. doi: 10.1111/j.1526-4637.2012.01328.x.

Paul JE, Arya A, Hurlburt L, Cheng J, Thabane L, Tidy A, Murthy Y. Femoral nerve block improves analgesia outcomes after total knee arthroplasty. *Anesthesiology* 2010; 113: 1144-1162.

Richman JM, Liu SS, Courpas G, Wong R, Rowlingson AJ, McGready J, Cohen SR, Wu CL. Does continuous peripheral nerve block provide superior pain control to opioids? A meta-analysis. *Anesth Analg*. 2006 Jan;102(1):248-57. doi: 10.1213/01.ANE.0000181289.09675.7D. PMID: 16368838.

Samineni AV, Seaver T, Sing DC, Salavati S, Tornetta P 3rd. Peripheral nerve blocks associated with shorter length of stay without increasing readmission rate for ankle open reduction internal fixation in the outpatient setting: A propensity-matched analysis*. J Foot Ankle Surg* 2021:S1067-2516(21)00399-9. doi: 10.1053/j.jfas.2021.10.017. Epub ahead of print. PMID: 34848109.

Sdrulla AD, Guan Y, Raja SN. Spinal cord stimulation: Clinical efficacy and potential mechanisms. *Pain Pract.* 2018;18(8):1048-1067. doi: 10.1111/papr.12692. Epub 2018 Apr 23. PMID: 29526043; PMCID: PMC6391880.

Spijker-Huiges A, et al. Costs and cost-effectiveness of epidural steroids for acute lumbosacral radicular syndrome in general practice: An economic evaluation alongside a pragmatic randomized control trial. *Spine. 2*014; 39: 2007-12. doi: 10.1097/BRS.0000000000000597.

Starr JB, Gold LS, McCormick Z, Suri P, Friedly J. Repeat procedures and prescription opioid use after lumbar medial branch nerve radiofrequency ablation in commercially insured patients. *Spine J.* 2020;20(3):344-351. doi: 10.1016/j.spinee.2019.10.005. Epub 2019 Oct 22. PMID: 31654808; PMCID: PMC7060813.

Yang AJ, Wagner G, Burnham T, McCormick ZL, Schneider BJ. Radiofrequency ablation for chronic posterior sacroiliac joint complex pain: A comprehensive review. *Pain Med.* 2021;22(Suppl 1):S9-S13. doi: 10.1093/pm/pnab021. PMID: 34308953.