



January 13, 2016

Thomas Frieden, MD, MPH
Director
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329-4027

Re: **Docket No. CDC-2015-0112**; Proposed 2016 Guideline for Prescribing Opioids for Chronic Pain

Dear Dr. Frieden:

The American Society of Anesthesiologists (ASA) and the American Society of Regional Anesthesia and Pain Medicine (ASRA) are pleased to comment on the draft Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain (Guideline), published in the Federal Register on December 14, 2015. We thank the CDC for recognizing that the prevention, assessment, and treatment of chronic pain is a challenge for physicians, and appreciate the work CDC is doing to reduce the burden of harm caused by the use of opioids.

ASA and ASRA support the federal government's efforts to reduce opioid overdose deaths, and support the majority of recommendations in the CDC Guideline. However, we are concerned that the Guideline would curtail perioperative physicians', which includes physician anesthesiologists, surgeons, and co-managing internists or hospitalists, ability to treat patients' acute pain after surgery, and any recommendations made by CDC need to balance the overprescribing of opioids for acute pain with perioperative physicians' imperative to treat post-surgical pain. ASA and ASRA are also concerned that the Guideline inaccurately portrays the effectiveness and risks of interventional procedures, which is particularly concerning since interventional pain procedures are a key non-opioid therapy to treat chronic pain. Below, we offer specific recommendations on how CDC can address these and other concerns in the Guideline.

General Comments

Target audience & pain medicine specialists as a resource

As recommended by ASA during the stakeholder reviewer comment period, we would like to thank the CDC for providing clarity that the Guideline does not apply to cancer pain patients. We agree that the appropriate target audience is primary care providers who are prescribing

opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care.

However, we request that CDC include language in the Guideline recommending that primary care providers use physician pain medicine specialists as a resource when diagnosing and treating patients with chronic pain and to refer their patients with complex chronic pain conditions to physician pain medicine specialists. Pain medicine is a recognized separate medical subspecialty by the American Board of Medical Specialties. Physicians specializing in pain medicine are required to participate in a one-year multidisciplinary pain fellowship in addition to successful completion of four years of medical school and four years of anesthesiology residency or appropriate residency training in physical medicine and rehabilitation, neurology, or psychiatry. Due to the complexities involved in the diagnosis and treatment of chronic pain, physician pain medicine specialists – with additional training and expertise – are a valuable resource for primary care providers treating patients with pain.

Insurance coverage

A major challenge in incorporating the Guideline in daily practice is that some of these recommendations may not be covered by the patient's insurance, which inhibits physicians' ability to treat patients using non-opioid approaches. We recommend that the Guideline clearly state that the federal government should encourage insurance coverage for therapies that would prevent opioid dose escalation or decrease. In addition, insurance coverage should include non-pharmacological therapies (all modalities available), and payers should reduce patient co-insurance and co-pays to encourage the use of non-pharmacological therapies.

Specific Comments

Measuring Opioid Effectiveness

In the Guideline, CDC emphasizes that evidence on long-term opioid therapy for chronic pain is insufficient to determine long-term benefits.¹ However, we would like to note that physicians can assess functional improvement when considering whether opioids are effective. For example, in treating a patient who is employed and regularly working, a physician can evaluate whether opioids enable the patient to continue to work. Although return-to-work is not generally considered a reliable outcome measure in clinical trials because the likelihood of returning to work when a person is on disability is so low, this can be a valuable measure for a prescribing physician. In addition, there is significant controversy around the topic of opioids and driving and their use in the work force. As such, the assessment endpoint of return to work in some settings becomes challenging due to existing laws and regulations.

Effects of Opioid Therapy for Acute Pain on Long-Term Use

ASA and ASRA are concerned that the Guideline could curtail perioperative physicians' ability to appropriately prescribe opioids to treat acute pain after surgery. CDC cites a study which found that opioid therapy prescribed for acute pain was associated with a greater likelihood of long-term use, but that same study also showed that patients prescribed non-

¹ CDC Proposed Guideline for Prescribing Opioids for Chronic Pain, 8-9.

steroidal anti-inflammatory drugs (NSAIDs) following surgery were found to have a similar pattern when compared with patients with no such prescription.² In addition, a primary reason that a patient may continue taking opioids seven days to one year after surgery is that pain can transition from acute pain to chronic pain. There are several large studies³ showing that acute surgical pain can become chronic pain, and one of the predictors for chronic pain is the severity of acute pain (1-7 days after surgery). CDC should encourage efforts, including perioperative physicians' appropriate prescribing of opioids and multimodal therapy for acute postsurgical pain, which helps prevent the development of chronic pain. For that reason, perioperative physicians' ability to treat patients after surgery should not be constrained by the CDC Guideline, particularly when prescribing opioids is the best treatment plan for that patient. We, however, agree that large quantities of opioids should not be prescribed for all post-surgical pain; rather, the quantity of prescribed opioids should be tailored to the severity of surgical trauma and the expected course of the postoperative pain which can only be determined by a trained perioperative physician.

Effectiveness of Alternative Treatments

In the Guideline, CDC states, "Interventional approaches such as epidural injection for certain conditions (e.g., lumbar radiculopathy) can provide short-term improvement in pain and in function that can facilitate exercise therapy (105–107). However, evidence has not demonstrated long-term benefit, and epidural injection has been associated with rare but serious adverse events, including loss of vision, stroke, paralysis, and death (108)."⁴

As noted by ASA, ASRA, and twelve other medical societies in a November 7, 2014 letter to the FDA Anesthetic and Analgesic Drug Products Advisory Committee, while complications with epidural steroid injections (ESIs) have been reported, and are likely underreported, serious complications are limited to isolated case reports. This is despite the large number of injections performed annually.⁵ No serious neurological complications have ever been reported in any prospective study of ESIs, regardless of approach or technique used, or anatomical area injected. A recently completed multi-institutional cohort of over 16,000 consecutive ESI procedures at all spine segments also reported no major complications.^{6 7 8} In addition, there is ample evidence demonstrating the effectiveness of ESIs in

² CDC Proposed Guideline for Prescribing Opioids for Chronic Pain, 10.

³ Kehlet H, Jensen TS, Woolf CJ. Persistent postsurgical pain: Risk factors and prevention. *Lancet*. 2006;367:1618-25.

⁴ CDC Proposed Guideline for Prescribing Opioids for Chronic Pain, 12.

⁵ Hirsch N, Manchikanti L. Analysis of the growth of epidural injections and costs in the Medicare population: A comparative evaluation of 1997, 2002, and 2006 data. *Pain Physician* 2011; 13:199-212.

⁶ El-Yahchouchi CA, Plataras CT, Maus TP, Carr CM, McCormick Z, Geske JR, Smuck M, Pingree MJ, Kennedy DJ. Complication rates of transforaminal and interlaminar epidural steroid injections: a multi-institutional study. *International Spine Intervention Society – 2014 22nd Annual Scientific Meeting Research Abstracts*. *Pain Med* 2014; 15:1436–1446.

⁷ Kennedy DJ, Plataras CT, Pingree MJ, Smuck M, Maus TP, Geske JR, El-Yahchouchi CA, Schneider BJ, Nahm L, McCormick Z, Kennedy DJ. Delayed complications in interventional pain procedures: A multi-institutional study. *International Spine Intervention Society- 2014 22nd Annual Scientific Meeting Research Abstracts*. *Pain Med*; 15:1436–1446.

⁸ Carr CM, Plataras CT, Pingree MJ, Smuck M, Maus TP, Geske JR, El-Yahchouchi CA, McCormick Z, Kennedy DJ. Adverse event rates in interventional spine procedures: A multi-institutional study. *International Spine Intervention Society – 2014 22nd Annual Scientific Meeting Research Abstracts*. *Pain Med*; 15:1436–1446.

reducing and eliminating pain, improving function, decreasing reliance on opioids, and eliminating the need for surgery for many patients.⁹

Therefore, we recommend that CDC revise the language to state:

Interventional approaches such as epidural injections, radiofrequency denervation and spinal cord stimulation for certain chronic pain diagnosis can provide short-term and long-term improvement in pain and in function that can facilitate exercise therapy with return to functionality.¹⁰ There are an extremely small number of complications associated with these interventional pain procedures, far less than the deaths from the chronic opioid therapy for chronic pain.

The study cited above in our revised language reviewed the efficacy of radiofrequency ablation for chronic low back pain associated with lumbar facet joints, sacroiliac joints, discogenic low back pain and the coccyx. The results concluded that there can be a significant benefit of radiofrequency ablation for lumbar facet joints and sacroiliac joints.

Recommendation #1

To make the available options clear to the prescribing physician, we propose that CDC revise Recommendation #1 to include examples of nonpharmacological and non-opioid pharmacological therapies. We propose the recommendation state:

Nonpharmacologic therapy (e.g. interventional pain procedures) and non-opioid 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.

In the discussion on Recommendation #1, CDC states, “Nonopioid pharmacologic therapies are not generally associated with drug dependence, and the numbers of fatal overdoses associated with nonopioid medications are a fraction of those associated with opioid medications (contextual evidence review).”¹¹

Per the comments in the above section, *Effectiveness of Alternative Treatments*, we recommend that CDC add the following language with respect to recommendation #1:

When performed by a pain medicine physician, there are an extremely small number of complications associated with interventional therapies, such as epidural injections, radiofrequency denervation, and spinal cord stimulation, and the complication rate is far lower than the complication rate for chronic opioid therapy for chronic pain.

⁹ Bogduk N (ed). Practice Guidelines for Spinal Diagnostic and Treatment Procedures, 2nd edn. International Spine Intervention Society, San Francisco, 2013.

¹⁰ Legget LE, Soril LJJ, Lorenzetti DL, Noseworthy T, Steadman R, Tiwana S, Clement F. Radiofrequency ablation for chronic low back pain: A systematic review of randomized controlled trials. Pain Research & Management. 2014; 19(5): e146-53.

¹¹ CDC Proposed Guideline for Prescribing Opioids for Chronic Pain, 18.

The Guideline later provides that for opioids, “Clinically meaningful improvement has been defined as a 30% improvement in scores for both pain and function.”¹² For interventional pain therapies, “clinically meaningful improvement” has always been defined as a 50% improvement in scores for both pain and function. With the bar being set higher for interventional therapies, CDC is not comparing the effectiveness of interventional therapies and opioids on equal ground and is undervaluing the effectiveness of interventional therapies in treating chronic pain.

Also mentioned in the discussion on Recommendation #1, the Guideline addresses nonopioid pharmacologic therapies, such as NSAIDs and anticonvulsants to treat chronic pain. We are supportive of additional education for practitioners on these treatment options.

Recommendation #6

The proposed Guideline states:

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.

We propose the following revisions and recommend that CDC remove the reference to “major” surgery because even minor surgery may require opioids for more than three days:

When opioids are used for acute pain, providers should prescribe the lowest effective dose of short-acting opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three or fewer days will usually be sufficient for non-traumatic pain not related to surgery.

Recommendation #7

With respect to Recommendation #7, under the section on *Considerations for Tapering Opioids*, we propose that CDC add among other modalities of therapy, interventional pain procedures, and suggest that physicians with an expertise in addiction and physician pain medicine specialists be utilized when a patient requires a tapering plan. In addition, such procedures and treatments should be covered by insurance.

Recommendation #9

We support the recommendation that providers utilize prescription drug monitoring programs (PDMP) to determine whether the patient is receiving high opioid dosages or dangerous combinations that put him or her at high risk for overdose. PDMPs are important clinical tools for physicians delivering high quality care to patients suffering from acute and chronic pain. PDMPs provide physicians a view of the drugs that their patients are receiving from other prescribers or pharmacies and help them decide whether to prescribe controlled substances. Because PDMPs can enhance quality care and patient safety, we support including this recommendation in the Guideline.

¹² *Id.* at 19.

Recommendation #10

In the discussion on Recommendation #10, the Guideline states, “Experts noted that in addition to direct costs of urine drug testing, which are often not fully covered by insurance and can be a burden for patients, provider time is needed to interpret, confirm, and communicate results.”¹³ We recommend that CDC work with the Centers for Medicare & Medicaid Services (CMS) to ensure that physicians are reimbursed for providing urine drug testing. CMS should develop a CPT code for carrying out this activity, and CDC should coordinate with CMS to ensure that physicians are not denied payment for appropriate use of this service.

We also recommend that urine testing for high morphine equivalent patients occur more frequently.

Recommendation #11

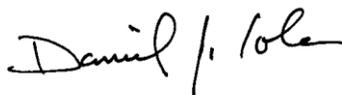
We support the education of the risks associated with the concomitant use of benzodiazepine and opioids, and additional education should be offered to prescribing physicians.

Recommendation #12

We continue to question whether this recommendation should be included in the Guideline; it seems to dictate the correct form of treatment for opioid use disorder rather than relate to the prescribing of opioids for chronic pain.

ASA and ASRA are pleased to have the opportunity to comment on the Guideline and look forward to working with the CDC to ensure both the safe prescribing by physicians and that the needs of patients are met.

Sincerely,



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¹³ *Id.* at 31.