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Centers for Disease Control and Prevention
1600 Clifton Road NE, Mailstop S106–9
Atlanta, GA 30329

RE: [Docket No. CDC-2020-0029] Management of Acute and Chronic Pain: Request for Comment

On behalf of the American Society of Interventional Pain Physicians (ASIPP), 50 state societies of interventional pain physicians, Society of Interventional Pain Management Surgery Centers (SIPMS), interventional pain management centers and pain physicians across the country, more importantly, millions of chronic pain patients, we are grateful to you for improving pain care.

We would like to thank you for the proposal for updates to the Centers for Disease Control and Prevention (CDC) guideline for prescribing opioids. We were not aware of the work, membership, or Opioid Workgroup. We understand the impact of chronic pain, opioids in chronic pain, published CDC guidelines, and the multitude of changes made in the final guideline, which was intended for primary care physicians. The implementation was followed by clarifications from CDC and the Department for Health and Human Services (HHS).

We would like you to consider the hard work performed by the Interagency Task Force, consisting of 29 members, with 8 federal members, including those from multiple organizations, who developed the CDC guidance. Extensive review of the literature and comprehensive development of recommendations resulted in the Pain Management Best Practices final report published on May 9, 2019.

Consequently:

1. Please utilize the Inter-Agency Task Force recommendations in its entirety for opioid prescribing, interventional techniques including neuromodulation.

2. Please postpone the final decision due to the COVID-19 pandemic.

3. Please include the practitioner community along with CMS officials.

4. Please consider and include only the systematic reviews and guidelines performed by experts in the pain management field and relevant societies developing evidence-based guidelines.

The Pain Management Best Practices Inter-Agency Task Force (Final Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations. May 9, 2019. https://www.hhs.gov/ash/advisory-committees/pain/reports/index.html) identified the following gaps and provided appropriate recommendations. These recommendations emphasized the inclusion of appropriate

interventional techniques in a management algorithm showing interventional procedures as a third step in the management of chronic pain with 5 steps (Enclosed Fig. 11). The best practice recommendations extensively recommended various types of interventional techniques and neuromodulation based on evidence based principles with extensive evidence available when it is appropriately conducted without substantial confluence of interest as many of the members of CDC guidelines and AHRQ have repeatedly exhibited favoring health insurers, over public safety and patient access to treatments.

2.1 APPROACHES TO PAIN MANAGEMENT

GAP 1: Current inconsistencies and fragmentation of pain care limit best practices and patient outcomes. A coherent policy for pain management for all relevant stakeholders is needed.

> **RECOMMENDATION 1B:**
> Encourage the use of guidelines that are informed by evidence and creating by **specialty organizations and associations that are experts in the treatment of certain pain conditions** that result from a variety of medical conditions or in different special populations.

2.2 MEDICATION

GAP 2: Opioids are often used early in pain treatment. There has been minimal pain education in medical school and residency programs, and little guidance for primary care physicians or providers on appropriate pain treatment approaches.

> **RECOMMENDATION 2E:** CMS and private payers should provide reimbursement that aligns with the medication guidelines the Task Force has described. Private payers and CMS should provide more flexibility in designing reimbursement models.

GAP 3: There is often a lack of understanding and education regarding the clinical indication and effective use of non-opioid medications for acute and chronic pain management.

2.4 INTERVENTIONAL PROCEDURES

GAP 1: Interventional pain procedures can provide diagnostic information when evaluating patients in pain and provide pain relief. A comprehensive assessment by a skilled pain specialist is necessary to identify which procedure is indicated for a given patient's pain syndrome. Unfortunately, pain specialists are typically not involved in the multidisciplinary approaches of diagnosing and treating a pain patient early enough in his or her treatment, which can lead to suboptimal patient outcomes.

> **RECOMMENDATION 1A: Adopt well-researched interventional pain guidelines to guide the appropriate use** of interventional pain procedures as a component of a multidisciplinary approach to the pain patient. Guidelines are particularly important for guiding the collaboration of primary care physicians and pain medicine specialists.
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> **RECOMMENDATION 1B:** Conduct additional clinical research that establishes how interventions work in conjunction with other approaches in the process of caring for patients with chronic pain, especially early in the process, when combined appropriately with goal-directed rehabilitation and appropriate medications.

RECOMMENDATION 1C: Establish criteria-based guidelines for properly credentialing clinicians who are appropriately trained in using interventional techniques to help diagnose, treat, and manage patients with chronic pain.

GAP 2: Inconsistencies and frequent delays exist in insurance coverage for interventional pain techniques that are clinically appropriate for a particular condition and context.

These are to a great extent based on inconsistent guidelines with a confluence of interest developed by AHRQ.

RECOMMENDATION 2A: Encourage CMS and private payers to provide consistent and timely insurance coverage for **evidence-informed interventional procedures** early in the course of treatment when clinically appropriate. These procedures can be paired with medication and other therapies to improve function and quality of life.

RECOMMENDATION 2B: CMS and other payers must restore reimbursement to nonhospital sites of service to improve access and lower the cost of interventional procedures.

This section clearly shows various interventional techniques utilized in managing chronic pain with appropriate evidence, with interventional procedures in the center of the spectrum of the 5 modalities of treatments (as shown in Fig. 11). Also illustrated are various interventional techniques with the degree of complexity in the best practices model as shown in Fig. 12. This section also highlights the significant literature available on multiple interventional techniques and neuromodulation. Further, there have been numerous other publications since the publication or consideration of the literature in this manuscript.. We are also enclosing additional references for consideration. We will be happy to provide you with any additional information you would like

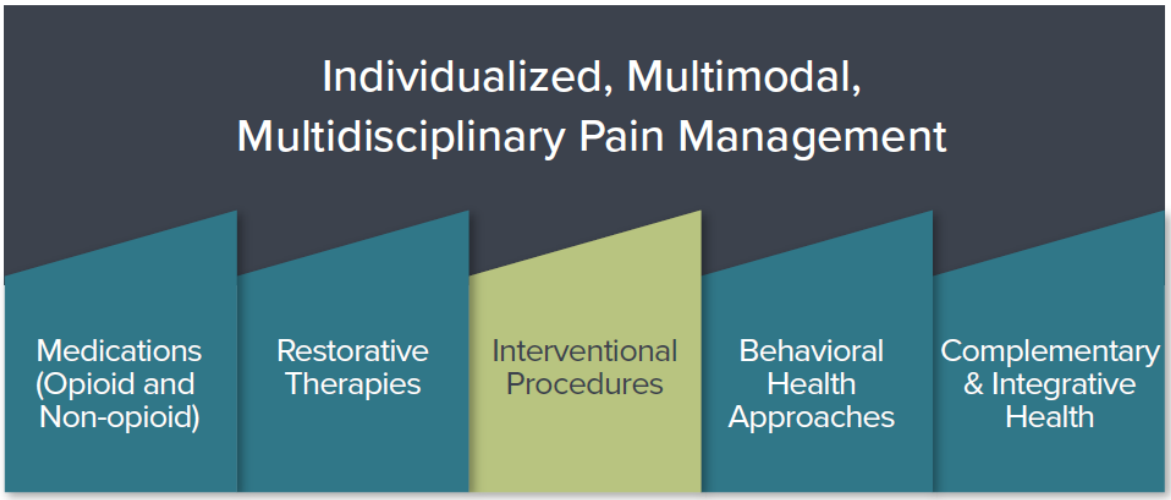

Figure 11: Interventional Procedures Are One of Five Treatment Approaches to Pain Management

Source: U.S. Department of Health and Human Services. Pain Management Best Practices Inter-Agency Task Force. Final Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations. May 9, 2019. https://www.hhs.gov/ash/advisory-committees/pain/reports/index.html

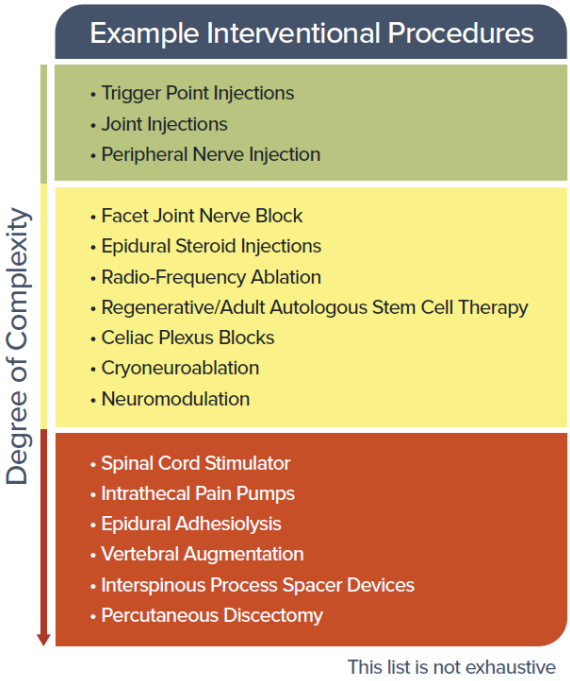

Figure 12: Interventional Procedures Vary by Degree of Complexity and Invasiveness

Source: U.S. Department of Health and Human Services. Pain Management Best Practices Inter-Agency Task Force. Final Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations. May 9, 2019. https://www.hhs.gov/ash/advisory-committees/pain/reports/index.html

Background

In 2016, the CDC published opioid guidelines for primary care physicians. During the development of these guidelines, even though it was dominated by Roger Chou from effectiveness healthcare programs of AHRQ, it had recommended significant use of interventional techniques. However, the final version removed these recommendations and made it quite incoherent. These guidelines intended for primary care physicians were adapted by various specialties, and finally, were made into regulations by the boards of medical licensures, which became mandatory. Some legislators also have made them mandatory. This created significant issues from pro-opioid interests by concerned physicians, patients, and a large outcry by the pro-opioid lobby. Overall guidelines have been extremely effective, along with other guidelines and to some extent education, and the Drug Enforcement Agency (DEA) and Food and Drug Administration (FDA) actions. Even then, HHS and the CDC were forced to publish retractions.

Systematic Reviews

Thus far, systematic reviews produced by effectiveness health care or AHRQ, have created substantial friction among professional society guidelines, professional societies, and the public themselves. These systematic reviews are funded by taxpayer dollars. There will not be any new information in these systematic reviews, only promotions for the participants and authors. Lastly, there are financial conflicts with the participants and authors even though these are government funded through tax payer dollars.

Scope of Updated Guidelines

It is admirable that the guidelines will provide additional detail regarding non-pharmacologic and non-opioid pharmacologic therapies for chronic pain. However, our major concern continues to be involvement of the individuals with special interests, either personally, professionally, or academically. There is substantial evidence in available literature and these unbiased outside sources should be utilized. This will,

in effect, save $3-$5 million, or even more based on how much will be budgeted from the taxpayer dollars. Since AHRQ has no significant funding, it appears these funds may be coming from elsewhere, these funds should be utilized for further progress of research in improving care for chronic pain patients rather than reducing access. Other goals are also appropriate in reference to acute pain and opioid tapering. Even then, these systematic reviews must come from public sources and must be published in peer-reviewed journals in the United States without conflicts of interest for individuals participating in preparing systematic reviews.

Requesting the establishment of input from a board of scientific counselor expert workgroup may be appropriate, again based on the type of membership and if they have any clinical experience. Just being a physician with extensive bias does not qualify them in managing chronic pain, so one should be not only expert in the synthesis of evidence, which should be consistent with the philosophy of true evidence-based medicine and real world evidence rather than individual experiences and ideologically prejudiced ideas. Clinical experience is crucial in preparing the guidelines as it has been stated by the editor in chief of the *New England Journal of Medicine* and *Lancet.*

> Quote from Richard Horton, editor-in-chief of the *Lancet,* "The case against science is straightforward: much of the scientific literature, perhaps half, may simply be untrue. Afflicted by studies with small sample sizes, tiny effects, invalid exploratory analyses, and flagrant conflicts of interest, together with an obsession for pursuing fashionable trends of dubious importance, science has taken a turn towards darkness."
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> Quote from Marcia Angell, former editor-in-chief of the *New England Journal of Medicine*, "It is simply no longer possible to believe much of the clinical research that is published, or to rely on the judgement of trusted physicians or authoritative medical guidelines. I take no pleasure in this conclusion, which I reached slowly and reluctantly over my two decades as an editor of the *New England Journal of Medicine*.

As you are aware, Cochrane collaboration has been criticized substantially for their bias and they even terminated multiple board members. In the same manner, *Lancet* and *New England Journal of Medicine* have withdrawn a multitude of manuscripts for their inaccuracies, which indicates their sloppiness. If more than 50% of the manuscripts are inadequate and probably 90% with Cochrane collaboration, the physician community and the public in general have no trust in these organizations.

Consequently, please consider these comments and develop appropriate guidance. The public has gotten used to the present ones. Unless there are going to be significant improvements, there is no point in developing additional guidelines.

ASIPP is a not-for-profit professional organization founded in 1998 now comprising over 4,500 interventional pain physicians and other practitioners who are dedicated to ensuring safe, appropriate and equal access to essential pain management services for patients across the country suffering with chronic and acute pain. There are approximately 8,500 appropriately trained and qualified physicians practicing interventional pain management in the United States. ASIPP is comprised of 50 affiliated state societies, and the Puerto Rico Society of Interventional Pain Physicians.

SIPMS is a not-for-profit professional organization founded in 2005, with membership involving surgical centers focusing on interventional pain management, dedicated to ensuring safe, appropriate, and equal access to essential pain management services for patients across the country suffering with chronic pain. There are approximately 500 surgery centers across the nation approved by Medicare providing or solely or an overwhelming majority of interventional pain management services.

Interventional pain management is defined as the discipline of medicine devoted to the diagnosis and treatment of pain related disorders principally with the application of interventional techniques in managing sub-acute, chronic, persistent, and intractable pain, independently or in conjunction with other modalities of treatment (The National Uniform Claims Committee. Specialty Designation for Interventional Pain Management- 09. www.cms.hhs.gov/transmittals/Downloads/r1779b3.pdf).

Interventional pain management techniques are minimally invasive procedures including, percutaneous precision needle placement, with placement of drugs in targeted areas or ablation of targeted nerves; and some surgical techniques such as laser or endoscopic diskectomy, intrathecal infusion pumps and spinal cord stimulators, for the diagnosis and management of chronic, persistent or intractable pain (Medicare Payment Advisory Commission. Report to the Congress: Paying for interventional pain services in ambulatory settings. Washington, DC: MedPAC. December. 2001. www.medpac.gov).

Thank you for your consideration. If you have any questions, please feel free to contact us.

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