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Request for Public Comments on the Pain Management Best Practices Inter-Agency Task Force Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations [Open Letter]

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Vanila M. Singh, MD
Chief Medical Officer
U.S. Department of Health and Human Services
Office of the Assistant Secretary of Health
200 Independence Avenue, SW
Washington DC 20201

Re: HHS–OS–2018–0027; Request for Public Comments on the Pain Management Best Practices Inter-Agency Task Force Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations

Dear Dr. Singh:

On behalf of the American Medical Association (AMA) and our physician and medical student members, the AMA commends the Pain Management Best Practices Task Force for its authoritative, evidence-based "Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations" (Draft Report). The AMA believes that if the Draft Report recommendations are implemented, it will not only improve pain care for America's patients, but also help end the nation's opioid epidemic.

The Draft Report provides an in-depth discussion of the balance needed between medical evidence, policy, and patient compassion alongside the realities of the nation's opioid epidemic, which continues to cause unprecedented levels of opioid-related harm. When finalized, the Draft Report and recommendations could potentially spur a shift in public policy, as well as private health insurer, pharmacy, and pharmacy benefit management (PBM) practices, to protect patients with pain from arbitrary, non-consensual tapering of opioid analgesics and denials of care, and to increase support for comprehensive, multimodal pain management practices.

In each of the four main sections of the Draft Report, the AMA is supportive of nearly all of their 150+ recommendations. While we have not commented on each recommendation, our comments below highlight some of the most important areas of agreement while providing feedback and suggestions to further improve or clarify some of the recommendations.

It is important to note at the outset that the AMA strongly supports the Draft Report's clear recognition that policies and practices that only promote, prioritize or pay for minimizing prescription opioid prescribing not only run the risk of undertreating pain, but they may lead to sub-optimal outcomes, increased stigma and ongoing barriers to care. We strongly support the Draft Report's recommendations for health insurance plans, PBMs and other payer policies to be changed and aligned to support comprehensive multimodal, multidisciplinary, restorative pain care. This includes removing administrative and financial barriers (e.g., prior authorization, inappropriate specialty tiering in formularies, prohibitive cost-sharing) as well as supporting payment policies that will promote optimal

pain care. The report makes clear that the barriers are pervasive and harm patients, including these striking passages:

> *"multidisciplinary, multimodal approaches to acute and chronic pain are often not supported in time and resources, leaving clinicians with few options to treat often challenging and complex underlying conditions."*
>
> *"The recent advent of retail pharmacies limiting the duration of prescriptions, making changes to dosage, amounts, or placing restrictive barriers to obtaining properly prescribed pain medications has had the unintended consequence of limiting access to pain care. Without access to sufficient pain care, many patients face unnecessary medical complications, prolonged suffering, and increased risk for psychiatric conditions."*

The AMA is deeply concerned that corporate and retail pharmacy and PBM practices are having the unintended consequence of limiting access to pain care—leading to medical complications, heightened stigma, and increased pain. The Draft Report is an important national acknowledgment that these policies need further investigation and re-examination to help ensure patients with pain can receive the type of comprehensive, multidisciplinary, multimodal care that pain experts support and patients deserve. The AMA supports the Draft Report's comprehensive discussion to-date of restorative therapies, interventional procedures, behavioral health approaches, and complementary and integrative health strategies. This information can and should be used going forward as a roadmap for discussions with policymakers regarding what options should be on the table for coverage by payers and PBMs.

Comments on Specific Recommendations

Section 2–Clinical Best Practices

Recommendation 2.1.1-2b is the type of key recommendation that underpins the Draft Report and the AMA strongly supports this recommendation:

> *Emphasize the following in guidelines, which provide an initial pathway to facilitate clinical decision making:*
>
> - *Individualized treatment as the primary goal of acute pain management, accounting for patient variability with regard to factors such as comorbidities, severity of conditions, surgical variability, geographic considerations, and community/hospital resources.*
> - *Improved pain control, faster recovery, improved rehabilitation with earlier mobilization, less risk for blood clots and pulmonary embolus, and mitigation of excess opioid exposure.*

The Draft Report's emphasis on individualized treatment, moreover, effectively refutes the common policy practice of using opioid dose thresholds alone to distinguish appropriate from inappropriate care. The AMA appreciates the strong evidence base and citations in support of the fact that:

> *The idea of a ceiling dose of opioids has been put forward, but establishing such a ceiling is difficult, and the precise level for such a ceiling has not been established. The risk of overdose increases with the dose, but the therapeutic window is highly variable.*

The AMA does support the concept put forward by the Centers for Disease Control and Prevention (CDC) that opioid analgesics should only be prescribed when their benefits outweigh their risks and, if that is the case, then the lowest effective dose should be prescribed for the shortest effective duration. But as the Draft Report points out multiple times, the CDC's voluntary guidance has been misapplied, there is considerable pressure put on physicians to reduce opioid prescribing to CDC thresholds, many states have enacted prescribing thresholds based on CDC guidelines, and patients have suffered as a result. For this reason, the AMA supports nearly all the recommendations in Section 2.2 and urges that they be finalized. We offer the following specific comments on several recommendations in this section.

First, Recommendations 1b and 1c suggest that "non-pain specialists should have timely early consultation with the pain medicine team and other specialists for the assessment of patients with complex pain to prevent complications and loss of function and to improve QoL." While consultations between physicians are commonplace, such a consultation may not be necessary for pain that is effectively managed by an oncologist, physiatrist, rheumatologist or other specialist who is able to effectively manage the patient's pain as well as treat the disease that is causing the pain. The AMA recommends that qualifying language be added to reflect that these types of consultations are recommended when pain control is not adequate, there are other concerning co-morbidities, or if the patient has increasing need for higher opioid doses.

Second, Recommendations 2d and 2e are both necessary, as patients' formularies and health insurance plans need to significantly improve affordable access to the many different non-opioid options listed in Section 2.2, including non-opioid medications and non-pharmacologic treatments for pain. That is rarely the case, which is why we encourage additional language in this section recommending that PBMs and payers not only be more transparent about non-opioid pharmacologic options in the formulary, but we also encourage a recommendation urging state and federal regulators to review payer and PBM formularies to ensure that non-opioid options are on low-cost tiers. It is untenable to tell physicians and patients to restrict the use of opioid analgesics when other forms of pain relief are not available or unaffordable. Policies and practices that only promote, prioritize or pay for minimizing prescription opioid prescribing risk undertreating pain and may lead to sub-optimal outcomes, increased stigma and ongoing barriers to care.

Third, the AMA supports Recommendations 4a and 4b, which aim to increase the use of buprenorphine in the treatment of pain. The Draft Report notes that buprenorphine is approved by the Food and Drug Administration for the treatment of pain and it is safer than morphine, hydrocodone, and oxycodone because it has a reduced potency for respiratory depression. As drafted, 4a is directed at hospital formularies and 4b addresses the need for coverage and reimbursement for buprenorphine treatment approaches. The Draft Report also notes, however, that physicians have faced challenges in getting authorization to prescribe buprenorphine for pain. The AMA suggests modifying 4b, therefore, to include eliminating prior authorization requirements for buprenorphine to facilitate its use in treating pain as well as opioid use disorder.

Section 2.2.1.1 "Prescription Drug Monitoring Programs"

This section provides important context for the appropriate balance between how PDMPs can help support clinical decisions made by physicians, but that "PDMPs are not to be used as tools to stop dispensing medications appropriately to those in need. For example, it is also important for pharmacists to know that doctors often work as teams and to ensure that 'doctor shopping' is a conclusion made after the pharmacist has made contact with the provider." In addition, it is important to note that prescribing decisions occur after screening, diagnosis, and consideration of the patient's full medical history. The PDMP plays a part, but is not a standalone screening, diagnostic or treatment tool.

The AMA and our AMA Opioid Task Force support physicians using PDMPs when clinically necessary, and we are pleased that use has increased from about 61 million queries in 2014 to more than 300 million in 2018. Yet, there is little evidence that PDMPs have had a positive effect on reducing opioid-related harms or helping identify or refer patients to screening or treatment for suspected opioid use disorder. While we appreciate and support the recommendations in this section, the Draft Report could go further and call for vendors and states to work toward integrating PDMP clinical data in such a way that better supports patient care.

The AMA also recommends that policymakers pay close attention to Recommendations 1d, 1e and 1f which collectively call for marrying PDMP use with clinical indications, evaluating whether PDMP mandates are creating overutilization problems, and encouraging electronic health record (EHR) vendors to continue to work to integrate PDMPs into EHR systems.

Section 2.2.1.2 Screening and Monitoring

This section provides a good discussion of how screening tools can help, but the Draft Report also notes the lack of evidence for some tools, such as urine drug screening, to be more widely used as an opioid prescribing risk mitigation tool. The AMA also agrees that patient pain treatment agreements can help clarify expectations for the patient and physician, but it is important to emphasize the Draft Report's finding that "the agreement should not be about simply getting a form signed or a means to 'fire' a patient for breaking the terms of the agreement; rather, it is a tool for facilitating a conversation between the clinician and the patient." Thus, while the AMA supports the general scope of the recommendations in this section, we urge an additional recommendation that the use of such screening tools should be determined by the physician in light of the individualized patient circumstances and characteristics. That is, some physicians may find that urine or other drug screening is not necessary for all patients; or that patient pain treatment agreements play a helpful role in ensuring open lines of communication.

Section 2.2.2 Overdose Prevention Education and Naloxone

The AMA agrees and supports efforts to increase access to naloxone to save lives from overdose, including co-prescribing by physicians to patients at risk of overdose. We strongly support the recommendations in this section and further urge HHS to support efforts for over-the-counter naloxone.

Section 2.3 Restorative Therapies

The AMA supports the recommendations in this section, but encourages a stronger recommendation to address the finding that "Use of restorative therapies is often challenged by incomplete or inconsistent

reimbursement policies." Specifically, we encourage a recommendation that goes further than only saying "there should be minimal barriers to accessing these modalities," to specify that "policymakers should closely evaluate and require health insurance companies to ensure that their formulary and benefit design packages include affordable access to a wide range of restorative therapies."

Section 2.4 Interventional Procedures

This section, like the rest of the Draft Report, provides important background and evidence on the wide range of therapies that may help patients with pain. We appreciate that "pain physician specialists are typically not involved in the multidisciplinary approaches of treating a pain patient early enough in his or her treatment," and we point out that is largely a function of whether a patient has an adequate health insurance network rather than a lack of interest by clinicians in having patients see a pain specialist. Recommendation 2a gets directly to this in the recommendation 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]."

Section 2.5.2 Chronic Pain Patients with Mental Health and Substance Use Comorbidities

The AMA supports increased recognition and treatment of patients with a substance use disorder who also have co-morbidities, which might include chronic pain. The recommendations in this section, which the AMA generally supports, need additional specificity to call for adequate insurance networks. Recommendation 1a, 1b, 1c, and 1d make valid points to increase referral patterns and use of specialists. This requires, however, that the patient has access to those specialists in the patient's health insurance network—and those specialists are actively seeing new patients. Therefore, the AMA urges additional language in this section to call on policymakers to require—as a condition of being allowed to sell insurance policies in a state—that state departments of insurance require payers to demonstrate network adequacy before a policy is allowed to be sold.

Section 2.7 Special Populations

The AMA supports the discussion in each of these sections, and commends the authors of the Draft Report for highlighting the unique needs of people of different ages, genders, with different medical conditions, ethnicities, and whose life experiences deserve individualized focus rather than one-size-fits-all solutions. Moving forward, the AMA urges increased attention and focus on pain and its relationship to health care disparities. This section represents a good starting point.

Section 3.1 Stigma

This section highlights an important, but largely unrecognized fact:

> *"Clinicians who treat acute and chronic pain, particularly with opioids and other controlled substances, experience stigma from colleagues and society in general that—in addition to fear of scrutiny from state medical boards and the DEA—dissuades many, particularly in primary care, from using opioids at all in the treatment of pain. PCPs are overburdened with time constraints, EHR demands, and other administrative tasks, which has led to unprecedented levels of burnout among physicians. Stigma, combined with the*

> *enhanced time required to effectively evaluate and treat pain, leads to over-referral and patient abandonment."*

The AMA strongly supports recommendation 2a to "Identify strategies to reduce stigma in opioid use so that it is never a barrier to patients receiving appropriate treatment, with all cautions and considerations for the management of their chronic pain conditions." This recommendation would go a long way in addressing the gap identified by the Draft Report:

> *The national crisis of illicit drug use, with overdose deaths, is confused with appropriate therapy for patients who are being treated for pain. This confusion has created a stigma that contributes to raise barriers to proper access to care.*

Section 3.2.1 Public Education

The AMA supports the recommendations in this section, and we are pleased to see examples such as Project ECHO (Extension of Community Health Outcomes) and Enhanced Recovery After Surgery (ERAS) as promising strategies to improve pain care. The AMA opioid microsite (www.end-opioid-epidemic.org) responds to recommendation 3a in that it provides more than 400 state-and specialty-society resources that are specific to the needs of physicians in states and to their particular specialty. In 2017, more than 549,000 physicians and other health care professionals across the nation completed continuing medical education trainings and accessed other education resources offered by the AMA, national medical associations, and state and specialty societies. We further support recommendation 2c, which calls on the Centers for Medicare and Medicaid Services and other payers to:

> *Recognize that the time spent educating and managing patients' expectations provides a significant value that reduces the length of hospital stays and improves patients' postoperative pain management, allowing for faster recovery through earlier PT and mobility that decreases the risk for postoperative complications (e.g., blood clots). CMS and other payors should compensate according to physician-patient time spent.*

Section 3.3 Access to Pain Care

The AMA supports the discussion in this section, and the clear recognition that:

> *The recent advent of retail pharmacies limiting the duration of prescriptions, making changes to dosage, amounts, or placing restrictive barriers to obtaining properly prescribed pain medications has had the unintended consequence of limiting access to pain care. Without access to sufficient pain care, many patients face unnecessary medical complications, prolonged suffering, and increased risk for psychiatric conditions.*

The AMA commends the authors of the Draft Report for identifying this, and the AMA will continue to work with the Administration and in states across the country to amend or reverse such policies. This is particularly important given recent reporting of patients taking their own lives and contemplating suicide as a result of not being able to access care. See, for example, the patient stories at https://docs.google.com/document/d/17uDel9qphd7EeBwHDRyOWdNCnoEbH9cw-PUGPjp1J1E/edit and the results of a recent online survey: https://www.painnewsnetwork.org/stories/2019/3/12/cdc-guideline-horrendous-impact-on-patients

Section 3.3.2 Insurance Coverage for Complex Management Situations

The AMA strongly supports the recommendations in this section. Although this section comes near the end of the Draft Report, it highlights one of the central reasons patients continue to suffer:

> *Patients with complex and persistent pain often experience barriers to care related to nonexistent or insufficient insurance coverage and reimbursement for evidence-based medical, behavioral, and complementary pain management services. Although the HHS National Pain Strategy calls for greater access and coverage for pain management services, there is a lack of uniformity in insurance coverage and lack of coverage alignment with current practice guidelines for pain management. This is particularly true for the coverage of nonpharmacologic and behavioral health interventions.*

The recommendations in this section further highlight the need for public and private payers to realign their policies to provide much greater support and coverage for non-opioid pain care as well as behavioral health care. In addition, recommendation 1a highlights the need to "Reimburse complex opioid and nonopioid management consistent with the time and resources required for patient education, safe evaluation, risk assessment, reevaluation, and integration of alternative, nonopioid modalities." This complements recommendation 4a, which emphasizes use of "a chronic disease management model." The AMA strongly supports this focus.

Section 4 Review of the CDC Guideline

The AMA supports the recommendations in this section. Prior to the publication of the CDC Guideline for Prescribing Opioids for Chronic Pain, the AMA emphasized its strong concern that policymakers, payers, pharmacies, and PBMs would take a document intended to help educate mainly primary care providers and turn it into policies that would lead to patients being refused care, stigmatized for using opioids, and non-consensually tapered to lower opioid doses based on the CDC Guideline. The AMA is pleased that the authors of the Draft Report listened to patient advocates, and the medical community, and reviewed the evidence of the impact of the CDC Guideline on patients with pain.

In line with the Draft Report's findings, AMA policy "affirms that some patients with acute or chronic pain can benefit from taking opioid pain medications at doses greater than generally recommended in the CDC Guideline for Prescribing Opioids for Chronic Pain and that such care may be medically necessary and appropriate." The Draft Report cites AMA concern "against misapplication of the CDC Guideline," and we would further stress that no entity should use MME (morphine milligram equivalents) thresholds as anything more than guidance. Furthermore, AMA policy states that "physicians should not be subject to professional discipline, loss of board certification, loss of clinical privileges, criminal prosecution, civil liability, or other penalties or practice limitations solely for prescribing opioids at a quantitative level above the MME thresholds found in the CDC Guideline for Prescribing Opioids."

The Draft Report further emphasizes that while there certainly is a role for the CDC Guideline and its guidance to reduce and mitigate opioid-related risk, "clinicians should be able to use their clinical judgment to determine opioid duration for their patients." While the authors of the Draft Report may be criticized for taking such a position, the AMA points out that the recommendations in this section simply focus on facts, including that "there is wide variation in factors that affect the optimal dose of opioids." The AMA strongly supports the recommendations in this section primarily because they call for

additional research and a focus on individualized patient care. Rather than non-consensual, forced tapering to an arbitrary MME, recommendation 4a, for example, says to "undertake opioid tapering or escalation with a thorough assessment of the risk-benefit ratio. This should be done in collaboration with the patient whenever possible."

In sum, the AMA supports having the CDC Guideline be viewed as called for in recommendation 8a: "guidance only for a general approach, with individualized patient care as the primary goal and the clinician then considering all modalities for best outcomes."

One final comment concerns the level of scholarship in the Draft Report. The AMA commends the authors for the nearly 450 individual citations buttressing the Draft Report recommendations. This will enable the Draft Report to serve as an excellent resource for further research and objective discussion of improving pain care in the United States.

Thank you for the opportunity to provide comments on this excellent report. The AMA looks forward to the final report and recommendations and is committed to working with the Task Force and policymakers to assist in their implementation. If you have any questions regarding this letter, please contact Margaret Garikes, Vice President of Federal Affairs, at margaret.garikes@ama-assn.org or 202-789-7409.

Sincerely,

James L. Madara, MD