



JAMES L. MADARA, MD
EXECUTIVE VICE PRESIDENT, CEO

ama-assn.org
t (312) 464-5000

June 16, 2020

Deborah Dowell, MD, MPH
Chief Medical Officer
National Center for Injury Prevention and Control
U.S. Centers for Disease Control and Prevention
4770 Buford Highway, NE
Atlanta, GA 30341

Re: Docket No. CDC-2020-0029

Dear Dr. Dowell:

On behalf of the American Medical Association (AMA) and our physician and medical student members, the AMA appreciates the opportunity to review and comment on the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain (CDC Guideline), originally published in 2016. We commend CDC's decision to open a public comment period to allow a broader group of important stakeholders the opportunity to provide their unique perspectives on the public health challenges faced by patients with pain, the unintended consequences of the CDC Guideline, and to provide constructive suggestions on how to revise and update the CDC Guideline to help it more effectively address the intersection of pain management, prescription opioid use, and opioid diversion, misuse, and unintentional overdose.

The AMA shares with CDC the goal of reducing the burden of harm from controlled substances, including opioid analgesics. The individual and family tragedies and societal costs attributable to opioid-related overdose, emergency department visits, deaths, and untreated substance use disorders are deeply concerning. To make meaningful progress towards ending this epidemic, a broad-based public health approach is required. This approach must balance patients' needs for comprehensive pain management services, including access to non-opioid pain care as well as opioid analgesics when clinically appropriate, with efforts to promote appropriate prescribing, reduce diversion and misuse, promote an understanding that substance use disorders are chronic conditions that respond well to evidence-based treatment, and expand access to treatment for individuals with substance use disorders.

The nation no longer has a prescription opioid-driven epidemic. However, we are now facing an unprecedented, multi-factorial and much more dangerous overdose and drug epidemic driven by heroin and illicitly manufactured fentanyl, fentanyl analogs, and stimulants. We can no longer afford to view increasing drug-related mortality through a prescription opioid-myopic lens. This is why the AMA continues its aggressive advocacy efforts in support of patients with pain and those with a substance use disorder as well as broad support for harm reduction policies and practices that address the wide range of factors affecting patients. The nation's opioid epidemic has never been just about prescription opioids, and we encourage CDC to take a broader view of how to help ensure patients have access to evidence-based comprehensive care that includes multidisciplinary, multimodal pain care options as well as efforts to remove the stigma that patients with pain experience on a regular basis. CDC has a great opportunity to

demonstrate its commitment to patients with pain through a detailed re-examination of the CDC Guideline, and the AMA urges CDC to work with physicians and patients to ensure that the revisions support patients with pain and the physicians who care for them.

In 2014, the AMA convened more than 25 (there are now 28 participating organizations) national, state, specialty, and other health care associations to form the AMA Opioid Task Force (Task Force) to coordinate efforts within organized medicine to help end the nation's opioid epidemic. Additionally, in acknowledgement of the needs of patients in pain and to identify a set of priorities for improving pain care that are actionable, the AMA Pain Care Task Force (PCTF) was formed in 2018. The newly formed PCTF is made up of representatives from 20 health care associations. This broad-based group of clinicians and experts is working collaboratively to improve pain care for patients by identifying actionable opportunities to improve medical education related to pain care, highlighting barriers to providing evidence-based pain care, and offering principles of pain care for physicians, payers, and policymakers. The work of the PCTF is complementary to the work of the Opioid Task force; the group has developed Principles of Care for Evidence-based Pain Management, as well as outlined systemic barriers and potential solutions in the delivery of pain care in the United States in an upcoming article in the *AMA Journal of Ethics*.¹

For the past three years, the AMA has measured several aspects where physicians have taken action to end the epidemic. The AMA has issued a report each year highlighting these areas. The 2019 report² was issued recently and shows that physicians and other health professionals are taking significant actions in the face of the epidemic, and some reports suggest that prescription opioid-related mortality may be leveling off. Key findings from the report include:

- **Opioid prescriptions decrease.** Opioid prescriptions decreased 33 percent (more than 80 million prescriptions) between 2013-2018, including more than 12 percent (more than 20 million prescriptions) between 2017-2018 alone.
- **Prescription drug monitoring programs (PDMP) use increases.** Nearly 2 million physicians and other health care professionals are registered to use state-based PDMPs, a 290 percent increase from 2014. Use of PDMPs increased to more than 450 million queries in 2018, a 56 percent increase from 2017 and a 651 percent increase from 2014.
- **Education increases.** In 2018, more than 700,000 physicians and other health care professionals completed medical education trainings and accessed other educational resources provided by the AMA and state and medical specialty societies. These materials included opioid prescribing, pain management, screening for substance use disorders, and related areas in 2018, up from 118,500 in 2015-16.
- **More physicians certified to treat opioid use disorder.** More than 87,000 physicians (and a growing number of nurse practitioners and physician assistants) are certified to provide in-office buprenorphine,³ up from 37,000 in 2016.

¹ Addressing Obstacles to Evidence-Informed Pain Care. AMA Pain Care Task Force. *AMA Journal of Ethics*® August 2020, Volume 22, Number 8: EXXX-XXX.

² AMA Opioid Task Force 2019 Progress Report. Available at <https://www.end-opioid-epidemic.org/wp-content/uploads/2019/06/AMA-Opioid-Task-Force-2019-Progress-Report-web-1.pdf>.

³ U.S. Substance Abuse and Mental Health Services Administration Program Data. Accessed June 10, 2020. Available at <https://www.samhsa.gov/medication-assisted-treatment/training-materials-resources/practitioner-program-data>.

- **Naloxone prescribing increases.** Access to naloxone has saved tens of thousands of lives. In 2018, the number of naloxone prescriptions reached a record high in the U.S. to more than 598,000 prescriptions, a 107 percent increase from 2017 and a 338 percent increase from 2016.

Recognizing that progress continues to be made on elements within physicians' control, the Task Force issued recommendations in 2019 to focus on ways in which policymakers can help end the changing epidemic.⁴ Those recommendations emphasize that multiple efforts need to be made to remove barriers to evidence-based care, including ensuring patients have access to the right treatment at the right time without administrative barriers or delay. These barriers, also recognized by the AMA PCTF, include prior authorization, step therapy, quantity limits, high cost-sharing, and coverage limitations on medications for treating opioid use disorder, as well as opioid and non-opioid medications and non-pharmaceutical therapies for managing pain. In many cases, health insurance plans and pharmacy benefit managers have used the 2016 CDC Guidelines to justify inappropriate one-size-fits-all restrictions on opioid analgesics while also maintaining restricted access to other therapies for pain.

There is no question that the nation's physicians have reduced opioid analgesic supply—both in volume and dose strength—but there has not been a concomitant increase in access to or affordability of evidence-based non-opioid alternatives. Both AMA Task Forces note that the therapies listed below may not be appropriate for all patients, which is why enhanced education and access to pain and palliative medicine specialists also is encompassed as part of this recommendation. As part of current and future efforts to reverse the nation's opioid epidemic, the Task Forces support increased research and access to evidence-based treatment, including:

- Medication, including non-opioid pain relievers, anticonvulsants, antidepressants, musculoskeletal agents, anxiolytics as well as opioid analgesics when appropriate. The Task Force notes that physicians and patients now face a multiplicity of new laws, guidelines, and policies from payers, PBMs, and national organizations, which are often contradictory.
- Restorative therapies, which include physical therapy, occupational therapy, physiotherapy, therapeutic exercise, osteopathic manipulative therapy (OMT), and other modalities such as massage and therapeutic ultrasound.
- Interventional procedures, such as neuromodulation, radio frequency ablation, peripheral nerve stimulation, central and peripheral nerve ablation, spine surgery and steroid injections, and other emerging interventional therapies as part of the multimodal pain care plan.

This recommendation further calls for more detailed regulatory review of formulary and benefit design by payers and PBMs to ensure that patients have affordable, timely access to evidence-based non-opioid alternatives, i.e., pharmacologic and non-pharmacologic. In conducting such reviews, policymakers are urged to work closely with physicians to ensure appropriate clinical input.

The Task Forces further affirm that some patients with acute or chronic pain can benefit from taking prescription opioid analgesics at doses that may be greater than guidelines or thresholds put forward by federal agencies, health insurance plans, pharmacy chains, pharmacy benefit management companies, and other advisory or regulatory bodies. The Task Force continues to urge physicians to make judicious and informed prescribing decisions to reduce the risk of opioid-related harms, but acknowledges that for some

⁴ 2019 AMA Opioid Task Force Recommendations for Policymakers. Available at <https://www.end-opioid-epidemic.org/recommendations-for-policymakers/>.

patients, opioid therapy, including when prescribed at doses greater than recommended by such entities, may be medically necessary and appropriate.

The AMA emphasizes that simply focusing on recommendations concerning opioid prescriptions is far from sufficient to have a meaningful impact on the nation's overdose and death epidemic. The earliest Task Force recommendations emphasized the need for patients to have access to evidence-based treatment not only for pain, but also for substance use disorders. The Task Force also has emphasized the need for harm reduction strategies and removing stigma—for patients with pain and for those with a mental illness or substance use disorder.

As the above measures of the Task Forces and physicians' actions indicate, progress has been made, but the epidemic has not ended. Thus, in 2019, the Task Force took direct aim at the barriers physicians and patients face in accessing evidence-based care, recommending:⁵

1. Remove prior authorization, step therapy, and other inappropriate administrative burdens or barriers that delay or deny care for FDA-approved medications used as part of medication-assisted treatment (MAT) for opioid use disorder (OUD).
2. Support assessment, referral, and treatment for co-occurring mental health disorders as well as enforce meaningful oversight and enforcement of state and federal mental health and substance use disorder parity laws.
3. Remove administrative and other barriers to comprehensive, multimodal, multidisciplinary pain care and rehabilitation programs.
4. Support maternal and child health by increasing access to evidence-based treatment, preserving families, and ensuring that policies are non-punitive.
5. Support reforms in the civil and criminal justice system that help ensure access to high quality, evidence-based care for OUD, including MAT.

The AMA recognizes that the above recommendations go beyond what CDC may be considering for revisions to the CDC Guideline, but we believe it is essential for CDC to specifically address the fact that the nation's overdose and death epidemic can no longer be viewed in a vacuum. A CDC Guideline only focused on "opioid prescribing" will perpetuate the fallacy that by restricting access to opioid analgesics, the nation's overdose and death epidemic will end. As CDC's own data makes clear, the epidemic has changed dramatically from one that was driven by opioid analgesics to one that now is fueled by illicitly manufactured fentanyl, fentanyl analogs, heroin and stimulants.⁶ In addition to recognizing the changing reality of the epidemic, we urge the CDC to not only specifically address the fact that the CDC Guideline is not intended to restrict patients' access to legitimate medical care—a point made in recent years by CDC officials elsewhere—but also to highlight the multifactorial nature of the epidemic.

The AMA urges the CDC Guideline start by recognizing the need for individualized care for patients with pain

⁵ AMA Opioid Task Force 2019 Recommendations for Policymakers. Available at <https://www.end-opioid-epidemic.org/wp-content/uploads/2019/05/2019-AMA-Opioid-Task-Force-Recommendations-FINAL.pdf>.

⁶ Ahmad FB, Rossen LM, Sutton P. Provisional drug overdose death counts. National Center for Health Statistics. 2020. Available at <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>.

As a starting point, the AMA points to the well-received recommendation from the U.S. Health and Human Services Pain Management Best Practices Interagency Task Force⁷ that patients experiencing pain need to be treated as individuals, not according to one-size-fits-all algorithms and policies that do not take individual patient's needs into account. A similar statement was made by the CDC in 2016 when it published the CDC Guideline, where the authors plainly stated that:

The recommendations in the guideline are voluntary, rather than prescriptive standards. They are based on emerging evidence, including observational studies or randomized clinical trials with notable limitations. Clinicians should consider the circumstances and *unique needs of each patient* when providing care.”⁸ (emphasis added)

Yet, the CDC Guideline also included multiple arbitrary dosage and quantity recommendations that have been consistently misapplied by state legislatures, national pharmacy chains, pharmacy benefit management companies, health insurance companies, and federal agencies. Early on, the AMA feared⁹ that the arbitrary opioid analgesic dosage and quantity thresholds appearing in the CDC Guideline would cause unintended consequences when used to severely limit individual treatment decisions made by physicians.

We believe it is instructive to detail some of the specific effects the CDC Guideline has had on patients and policies to highlight the urgent need for CDC to revise the CDC Guideline.

The CDC Guideline has harmed patients

It is clear that the CDC Guideline has harmed many patients¹⁰—so much so that in 2019, the CDC authors¹¹ and HHS issued long-overdue, but greatly appreciated, clarifications that states should not use the CDC Guideline to implement an arbitrary threshold:

Unfortunately, some policies and practices purportedly derived from the guideline have in fact been inconsistent with, and often go beyond, its recommendations. A consensus panel has highlighted these inconsistencies, which include inflexible application of recommended dosage and duration thresholds and policies that encourage hard limits and abrupt tapering of drug dosages, resulting in sudden opioid discontinuation or dismissal

⁷ “The Task Force emphasizes the importance of individualized patient-centered care in the diagnosis and treatment of acute and chronic pain.” U.S. Department of Health and Human Services (2019, May). Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations. Retrieved from U. S. Department of Health and Human Services website:

<https://www.hhs.gov/ash/advisorycommittees/pain/reports/index.html>.

⁸ Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: <http://dx.doi.org/10.15585/mmwr.rr6501e1>.

⁹ Letter from AMA Executive Vice President and CEO James L. Madara, MD, to CDC Director Thomas L. Frieden, MD, MPH. January 12, 2016. Available at <https://searchlf.ama-assn.org/undefined/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2Fcdc-opioid-guidelines-12jan2016.pdf>.

¹⁰ Beth D Darnall, David Juurlink, Robert D Kerns, Sean Mackey, et al., International Stakeholder Community of Pain Experts and Leaders Call for an Urgent Action on Forced Opioid Tapering, Pain Medicine, Volume 20, Issue 3, March 2019, Pages 429–433, <https://doi.org/10.1093/pm/pny228>.

¹¹ Deborah Dowell, M.D., M.P.H., Tamara Haegerich, Ph.D., Roger Chou, M.D. No Shortcuts to Safer Opioid Prescribing. June 13, 2019. N Engl J Med 2019; 380:2285-2287. DOI: 10.1056/NEJMp1904190.

of patients from a physician's practice. The panel also noted the potential for misapplication of the recommendations to populations outside the scope of the guideline. Such misapplication has been reported for patients with pain associated with cancer, surgical procedures, or acute sickle cell crises. There have also been reports of misapplication of the guideline's dosage thresholds to opioid agonists for treatment of opioid use disorder. Such actions are likely to result in harm to patients.

The AMA welcomed this clarification, and we offer specific recommendations below that we believe puts it into action to further the goal of individual care and provides the type of clear policy guidance needed by patients with pain. In addition, we also ask that CDC include patient advocates in its formal review of these and other comments as part of any revision to the CDC Guideline to ensure that patient needs are adequately addressed. Although population-level data may be relied on to help construct clinical guidance, pain is an intensely personal and conscious experience influenced by emotion, cognition, memory, interpersonal, racial and social context, and other factors. Patient-reported intensity of pain may not correlate with the magnitude or identifiable source of injury. Because objective tests for pain intensity (or even the presence or absence of pain) are still at a rudimentary stage of development, the best clinical approach in most circumstances is to assume that the patient is reporting a true experience.

Accepting a patient's complaint of pain as valid does not require clinical identification of a physical cause or demand the initiation of a specific treatment. It does, however, provide a foundation for assessment and the basis for developing an effective patient-physician dialogue and an approach to individualized, patient-centered treatment. Meaningful and appropriate treatments are best achieved via shared decision-making. Health disparities in pain management and legitimate access to opioid analgesics for pain remain evident, and clinically relevant differences in pain expression and responsiveness based on sex, race, ethnicity, and genetic constitution also exist. Based on feedback from patient groups, patients suffering from pain increasingly view themselves as collateral damage in efforts to restrict opioid prescribing decisions via state-based regulations and legislative mandates, and the CDC has itself acknowledged the CDC Guideline's negative effect on access for patients with legitimate medical needs. It is essential that this is addressed in a substantive, meaningful manner.

The CDC Guideline has been misapplied as a hard policy threshold by states, health plans, pharmacy chains, and PBMs

Examples of inappropriate policies with specific limits or policies that misapply the CDC Guideline in different ways and have resulted in specific harm to patients include the following:

- Walmart's policy includes a 50MME or 7-day hard threshold for opioid prescribing;¹²
- CVS Caremark's policy has multiple restrictions, including a 7-day hard threshold for opioid prescribing;¹³
- OptumRx's policy is aligned with 2016 Guidelines;¹⁴

¹² See Walmart Opioid Stewardship, available at <https://corporate.walmart.com/stewardship>.

¹³ See CVS Caremark® Opioid Quantity Limits Pharmacy Reference Guide, available at https://www.caremark.com/portal/asset/Opioid_Reference_Guide.pdf.

¹⁴ "OptumRx drives opioid safety and prevention." OptumRx. <https://professionals.optumrx.com/resources/notice-resources/opioid-safety.html>.

- Walgreen’s Good Faith Dispensing Policy¹⁵ does not list specific thresholds, but the AMA has received numerous complaints about pharmacists refusing to fill a prescription because of “corporate policy.”
- Blue Cross-Blue Shield Association 7-day hard threshold;¹⁶
- United Healthcare 7-day, 90 MME hard threshold; and ¹⁷
- More than 30 states have enacted laws with opioid prescribing restrictions ranging from 3 to 14 days, including many with MME limits and other restrictions.¹⁸

These policies, moreover, have not withstood any meaningful evaluation or data analysis as to whether they have improved pain care or reduced opioid-related harms. There also are no data to suggest that payers have increased access to non-opioid pain care options. If one of the goals of the CDC Guideline was to increase access to non-opioid pain care, that has not been realized. Rather, there is evidence that payers continue to erect and support barriers to non-opioid pain care. A 2019 survey from the American Board of Pain Medicine¹⁹ found:

- 72 percent of pain medicine specialists said that they—or their patients—have been required to reduce the quantity or dose of medication they have prescribed;
- 92 percent of pain medicine specialists said that they have been required to submit a prior authorization for non-opioid pain care—with the physicians and their staff spending hours per day on such requests; and
- 66 percent of pain medicine specialists said that they have had to hire additional staff to handle the prior authorization requirements.

While the AMA understands that the apparent goal of the CDC Guideline was to reduce opioid prescribing, we believe the proper role of CDC is to improve pain care. It follows that a dedicated effort must be made to undo the damage from the misapplication of the CDC Guideline.

Recommendations to improve the CDC Guideline

Accordingly, the CDC Guideline could be substantially improved in three overarching ways. First, by incorporating some fundamental revisions that acknowledge that many patients experience pain that is not well controlled, substantially impairs their quality of life and/or functional status, stigmatizes them, and could be managed with more compassionate patient care. Second, by using the revised CDC Guideline as

¹⁵ “Walgreens Q & A Prepared for the New Hampshire Medical Society”

<https://www.nhms.org/sites/default/files/Pdfs/proofed%20walgreens%20policy%206-5-2013.pdf>.

¹⁶ ADDRESSING THE OPIOID CRISIS: Preventing Abuse and Ensuring Patients Receive the Right Care in the Right Setting. Blue Cross Blue Shield Association. September 2018. <https://www.bcbs.com/sites/default/files/file-attachments/page/Opioids%20Whitepaper.pdf>.

¹⁷ 2020 Opioid Readiness: UnitedHealthcare Medicare Advantage and Prescription Drug Plans Quick Reference Guide. United Healthcare. <https://www.uhcprovider.com/content/dam/provider/docs/public/resources/pharmacy/opioids/Provider-opioid-qr-2020.pdf>.

¹⁸ Prescribing Policies: States Confront Opioid Overdose Epidemic. National Conference of State Legislatures. June 30, 2019. Available at <https://www.ncsl.org/research/health/prescribing-policies-states-confront-opioid-overdose-epidemic.aspx>.

¹⁹ Second Annual Survey of Pain Medicine Specialists Highlights Continued Plight of Patients with Pain, and Barriers to Providing Multidisciplinary, Non-Opioid Care. American Board of Pain Medicine. Available at <http://abpm.org/uploads/files/abpm%20survey%202019-v3.pdf>.

part of a coordinated federal strategy to help ensure patients with pain receive comprehensive care delivered in a patient-centric approach. And third, by urging state legislatures, payers, pharmacy chains, pharmacy benefit management companies, and all other stakeholders to immediately suspend use of the CDC Guideline as an arbitrary policy to limit, discontinue or taper a patient's opioid therapy.

Recommendation 1

Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.

With respect to specific revisions, and in addition to the suggestions provided above, the AMA recommends the following revisions to the first recommendation of the 2016 CDC Guideline:

Non-pharmacologic therapy and non-opioid pharmacologic therapy are preferred for patients with chronic pain. Providers should consider using opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy, as appropriate. In order to achieve this goal, public and private payer policies must be fundamentally altered and aligned to support payment for non-pharmacologic treatments and multimodal, multidisciplinary pain care. In addition, more evidence must be developed to inform clinical decision-making on the use of nonpharmacologic approaches, and more clinicians need to be trained in their effective use.

The AMA's rationale for this revision starts with the fundamental principle that treatment decisions for patients with pain must be made on an individualized basis. Opioid therapy should only be used when the benefits outweigh the risks, but there is no question that some patients benefit from opioid therapy—including at doses that some may consider "high." As noted above, CDC authors of the CDC Guideline recognize that it has been used to deny access to legitimate pain care and non-consensually taper patients. The AMA urges CDC to specifically address this in the revised CDC Guideline.

We further urge CDC to support patients' access to a broad range of pharmacologic and non-pharmacologic options. Broad-based, effective implementation of this recommendation requires large scale changes in the public and private payer communities and better evidence to inform the most effective nonpharmacologic approach for various conditions. Furthermore, access to non-pharmacologic and non-opioid pharmacological treatments and reimbursement for them are often inadequate, especially for multidisciplinary care. The National Pain Strategy specifically identifies that a pressing need exists to assess insurer practices such as prior authorization, step therapy, fail-first protocols, specialty tier payment structures, and other limits on reimbursement for multidisciplinary care treatments that act as barriers to effective care. Telling physicians they must use non-opioid pain care options when payers and other make them financially or administratively unavailable is a Catch-22 that CDC needs to help end.

Recommendation 2

Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.

While we generally support the CDC Guideline's second recommendation, some situations exist where patients may have intractable pain and sufficient disability such that functional improvement is not possible, and relief of pain and suffering alone is a supportable primary goal. In an analogous fashion, some patients may demonstrate functional improvement, with limited changes in pain scores. Accordingly, the AMA recommends the following revisions:

Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function and should consider how therapy will be adjusted, including the potential for tapering and/or discontinuation, discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful benefit improvement in achieving treatment goals for improving or maintaining levels of pain and function that outweighs risks to patient safety.

The AMA strongly supports that physicians should, before starting long-term opioid therapy, establish treatment goals with all patients, including realistic goals for pain and function. Physicians should not initiate long-term opioid therapy without consideration of how therapy will be discontinued if benefits do not exceed risks. Physicians should continue opioid therapy only if there is clinically meaningful improvement in treatment goals for pain and function that outweighs risks to patient safety. We again emphasize that decisions to continue, taper or discontinue opioid therapy must be made in a shared decision-making construct between the patient and his or her physician.

Recommendation 3

Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy.

The AMA generally supports this recommendation, although it introduces a modifying term for benefits (realistic) that does not appear elsewhere in the CDC Guideline. Objective clinical determinations are best made on an individualized basis with the patient's specific clinical presentation helping guide the physician's decision-making and in consideration of the evidence-base supporting the treatment plan. Moreover, as noted above, the discussion between the physician and patient must account for the available treatments to the patient, i.e., the "realistic" factors of health insurance benefits, barriers, and financial considerations. Thus, the AMA recommends the following be added to the recommendation:

Clinicians are encouraged to have open and honest discussions with their patients so as to avoid stigmatizing the decision to start, continue, or discontinue opioids or non-opioid therapy. This discussion also must account for the treatment options accessible to the patient based on their health condition, social determinants of health (e.g. transportation, employment, childcare responsibilities, race, gender, age) and insurance coverage.

Recommendation 4

When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids.

We generally support this recommendation. We encourage CDC to include in its discussion acknowledgment that as a patient begins opioid therapy, there may be incremental changes to the dose

and/or quantity prescribed along with the type of opioid analgesic by itself or in combination with other pharmacologic options. Those incremental adjustments sometimes have been interpreted by a state PDMP and/or pharmacist as a new “start.” We are concerned that such a careful approach to identifying the precise combination of pharmacologic options could be flagged on a prescription drug monitoring program as indications wrongly interpreted as so-called “doctor shopping” and cause the patient to be inappropriately questioned by a pharmacist. The AMA strongly supports a pharmacist carrying out his or her corresponding responsibility under state and federal law, but the past few years are rife with examples of patients facing what amounts to interrogations at the pharmacy counter as well as denials of legitimate medication. The AMA urges CDC to provide strong guidance and support for physicians and pharmacists to work together rather than jump to conclusions about a patient’s PDMP report.

Recommendation 5

When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when increasing dosage to =50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to =90 MME/day or carefully justify a decision to titrate dosage to =90 MME/day.

As the AMA cautioned when CDC was originally considering using specific—yet arbitrary—numbers for this recommendation, we continue to urge CDC to revise this recommendation. On one hand, the AMA supports the underlying premise that physicians should prescribe the lowest effective dose and only increase dosage gradually. This is a common school of practice for physicians in treating any chronic disease. It is a general tenet of medical practice that any change to the treatment regimen is one made by considering the risks and benefits. We do not understand what CDC means by “additional precautions” in the discussion to this recommendation, and we are concerned that CDC’s implication that patients receiving higher doses may warrant additional scrutiny has been a primary factor in the stigmatization of patients with chronic pain.

The AMA wrote in 2016:

“this recommendation as currently stated has the potential to cause confusion, uncertainty, and conflicting institutional or state policies that may have unintended consequences. One likely consequence is that most insurers and other payers will use this recommendation to deny or impose new hurdles to coverage of any dose that exceeds the threshold. Another likely consequence is that patients experiencing pain who require a daily dose above 50 MME will face additional prejudice and stigma. While several states have enacted laws or regulations designed to modify clinical decision-making based on MMEs, analysis of the actual efficacy of these approaches and their effect on reducing overdose and pain management is lacking, including whether they may have unintended consequences.”

We were glad CDC recognized in 2019 the harms caused by the misapplication of this recommendation (and other CDC Guideline recommendations) that “results in hard limits or ‘cutting off’ opioids” or “abrupt tapering or sudden discontinuation of opioids” as well as its statement that “policies that mandate

hard limits conflict with the Guideline’s emphasis on individualized assessment of the benefits and risks of opioids given the specific circumstances and unique needs of each patient.”²⁰

Yet, the truth of the matter is that MME thresholds remain as hard policy by many health insurers, pharmacy chains, and PBMs. The AMA strongly urges CDC to add language to the revised CDC Guideline urging those entities to rescind these policies given the absence of data to suggest a relationship between the arbitrary thresholds and improved patient outcomes—as well as the harms done to patients as a result of inappropriate tapering or denials of care. As such, the AMA recommends recasting this recommendation in its entirety:

Before starting long-term opioid therapy, and at periodic intervals thereafter, physicians should establish and review treatment goals with all patients, including shared goals for pain and function. Physicians should initiate opioid therapy with the lowest effective dose. Continued opioid therapy and/or dose escalation should occur only if there is clinically meaningful improvement or maintenance in treatment goals for pain and function that outweighs risks to patient safety. Hard thresholds should never be used.

Recommendation 6

Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians 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 days or less will often be sufficient; more than seven days will rarely be needed.

The AMA stands by the same concerns that we expressed in 2016 that “The three-day limit imposed by this recommendation in the outpatient setting is arbitrary and the surrounding circumstances are clinically vague. If this recommendation is targeting post-surgical prescriptions (which would deviate from the stated goal of the Guidelines to apply to primary care), then an effort should be made to provide the supporting evidence base.”

As with Recommendation 5, the AMA recommends that Recommendation 6 clearly include CDC’s own admission concerning: “**Misapplication of recommendations to populations outside of the Guideline’s scope.** The Guideline is intended for primary care clinicians treating chronic pain for patients 18 and older. Examples of misapplication include applying the Guideline to patients in active cancer treatment, patients experiencing acute sickle cell crises, or patients experiencing post-surgical pain.”²¹

The AMA has heard from many physicians and patients from whom needed pain therapy with opioid analgesics was withheld based on a rationale that the treatment team was following the CDC guidance. Patients with sickle cell disease or advanced cancer have been accused of manufacturing acute pain and engaging in drug seeking behavior. We have heard from physicians and patients in hospice or who have

²⁰ CDC Advises Against Misapplication of the *Guideline for Prescribing Opioids for Chronic Pain*. U.S. Centers for Disease Control and Prevention. April 24, 2019. Available at <https://www.cdc.gov/media/releases/2019/s0424-advises-misapplication-guideline-prescribing-opioids.html>.

²¹ CDC Advises Against Misapplication of the *Guideline for Prescribing Opioids for Chronic Pain*. U.S. Centers for Disease Control and Prevention. April 24, 2019. Available at <https://www.cdc.gov/media/releases/2019/s0424-advises-misapplication-guideline-prescribing-opioids.html>.

cancer that opioid analgesics were denied because the prescribed amounts did not comply with the CDC Guideline. These unintended but predictable consequences add to the stigma, racial, and other biases that these patients already face. In revising its Guideline, the CDC must address these concerns. This includes any implication that long-term opioid therapy is automatically negative. That is, we urge CDC to remain focused on treatment recommendations rather than subjective statements that lend themselves toward further stigmatizing those who benefit from long-term opioid therapy.

The AMA therefore recommends the following revisions:

~~Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater in a quantity than needed only for the expected duration of pain severe enough to require opioids. Three or fewer days will often be sufficient; more than seven days will rarely be needed. Hard thresholds should never be used. Where such thresholds have been implemented based on the previous CDC Guideline, they should be eliminated.~~

Recommendation 7

Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians 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, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.

As we said in 2016, the AMA continues to agree with “the need to appropriately monitor patients during the onset of long-term therapy or after dosage escalation, but recommend that CDC pay close attention to comments received from various medical specialty societies, including those in the stakeholder review panel, to address the specific timeframes that might comprise this recommendation. While it may be somewhat nuanced, the last sentence in this recommendation does not accommodate a clinical situation where reducing the opioid dose may restore an appropriate risk/benefit ratio.”

In addition, we note that this recommendation is another example where CDC’s use of specific numbers has caused states to adopt the Guideline as hard policy. The requirement for more frequent evaluations may not seem an imposition, but for many patients, this comes with additional co-pays and co-insurance, the need to take time off from work or household requirements, and other burdens that are not imposed on patients with other chronic disease. The AMA understands that the intention of the CDC was not to impose additional burdens on patients or physicians, but that has been the effect.

The AMA asks, therefore, that the CDC acknowledge the burdens patients face. In addition, we recommend the last sentence should be revised to read as follows: “If benefits do not outweigh harms of continued opioid therapy, providers should work with patients to reduce opioid dosage and, if necessary, to discontinue opioids to prevent harm when possible.”

Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy at appropriate clinical intervals determined by the clinician. ~~every 3 months or more frequently.~~ If benefits do not outweigh harms of continued opioid therapy, clinicians should

optimize other available and affordable therapies and, if necessary, discuss with patients a shared plan to carefully and gradually lower dosages, ~~or to taper, or and~~ discontinue opioids.

Recommendation 8

Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians 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, higher opioid dosages (≥ 50 MME/day), or concurrent benzodiazepine use, are present.

We continue to generally agree with the language presented in Recommendation 8 as a prudent clinical approach, as well as the guidance offered on expanding the use of naloxone. However, as we pointed out previously, we continue to urge CDC to provide additional clarity to ensure that this recommendation does not cause unintended consequences. For example, the AMA encourages physicians to use PDMPs as part of the clinical decision-making process, but we urge CDC to state that a PDMP report, by itself, should not be used as grounds to deny care to a patient. We also urge CDC to state that drug testing, which may be a helpful adjunct in some practices to monitor compliance, should not be used to summarily “fire” patients who return non-compliant results. The CDC also should make clear that while there are risks for opioid use contributing to neonatal abstinence syndrome, pregnant women should not be denied appropriate pain care. And while there are clear risks associated with concomitant use of benzodiazepines and opioids, we urge CDC to provide the detailed evidence base of the risk while acknowledging that increased risk does not mean CDC blanket opposition.

The AMA remains concerned that the discussion of risk has increased stigma to patients with pain. Too many states, health insurers, pharmacy chains, and PBMs have adopted one-size-fits-all policies that attempt to address risk by putting so many restrictions on care that the new policies have increased harm.

We stand by our previous comments that:

In no case should a pregnant woman be treated as a criminal if she and her physician determine that opioids are needed, but that is how some policymakers have approached this clinical determination. In addition, a woman in pain deserves to have her pain treated; if the benefits of opioids outweigh the risks of harm, then that decision should be respected.

We continue to urge CDC to more fully reflect this delicate balance. Therefore, we recommend the following revisions to this recommendation:

Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid-related overdose, such as history of overdose, history of substance use disorder, or higher opioid dosages (≥ 50 MME), or concurrent benzodiazepine use, are present. Risk factors should be discussed with the patient, but no single risk factor should be used as a determining factor in decisions to discontinue or deny care.

Recommendation 9

Clinicians 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 opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians 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.

The AMA continues to support physicians’ use of effective PDMPs and offers new caution based on physicians’ and patients’ experience since publication of the CDC Guideline in 2016. We continue to urge CDC to recognize that PDMP data is only one type of information to help guide a physician’s clinical decisions. Moreover, it is only one piece of data available to pharmacists and any other authorized user of a state PDMP. Yet, PDMPs have been used to inappropriately tag physicians as “inappropriate prescribers” by pharmacy chains and patients as “doctor shoppers” by some pharmacists. The AMA does not support illegal activity, but a PDMP report, by itself, is almost always insufficient to identify illegal behavior.

While PDMPs can help identify patients receiving multiple prescriptions from multiple prescribers or dispensers, and this behavior is a risk factor for unintentional overdose, we believe the steps to be taken after identifying such individuals are much more complex and require further research and attention. While it is an important variable to quantify, we are concerned that PDMP reports have been used to deny care to patients—by physicians and pharmacies. Physicians are understandably afraid that a PDMP report identifying them as a “top prescriber” will result in investigations by law enforcement or a medical licensing board without taking into account the physician’s patient population. In turn, a patient who has multiple prescriptions from multiple prescribers and/or pharmacies is one who needs treatment, not law enforcement intervention. The AMA urges CDC to support this public health focus.

Accordingly, the AMA recommends the following revisions:

Clinicians should review the patient’s history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to help inform the provider’s clinical decision-making. determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should continue to review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy at clinically appropriate intervals. PDMP reports raising questions should be carefully examined but not used, by themselves, as reasons to discontinue or deny care to the patient. , ranging from every prescription to every 3 months.

Recommendation 10

When prescribing opioids for chronic pain, clinicians 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.

Similar to above concerns, we continue to point out that the evidence used by CDC in 2016 still does not support the conclusion that urine drug testing improves outcomes in patients receiving opioids for chronic pain. Since 2016, we have additional concerns that urine drug testing has been used to summarily discontinue treatment for some patients who either do not complete a test on a mandated schedule or

return a result suggesting some level of non-compliance. While a urine drug screen can serve as an objective measure as part of a broader risk mitigation strategy when designing treatment and monitoring strategies for individual patients on chronic opioid therapy, it is not a panacea and should not be used as a “gotcha” element. Unfortunately, the CDC Guideline encourages that belief and approach.

In addition, we are concerned by the continuing significant knowledge gaps regarding the use of interpretation of urine drug tests in primary care and different monitoring frequencies may be required based on individual patient variables. Furthermore, the wide variability in insurance coverage is not insignificant, with implications for physician reimbursement for interpretation, to the potential costs for both private and public payer systems. Of equal, if not more significance, is the fact that many patients currently have to pay for urine testing out of pocket, which may impact their ability to comply with a pain care agreement.

Therefore, the AMA recommends the following revisions:

When prescribing opioids for chronic pain, clinicians’ potential use of urine drug testing should be made in consultation with the patient, including discussion of the limitations of such testing and assurances that test results are only one factor in ongoing treatment decisions. Urine drug testing should not, by itself, be a determining factor in whether to discontinue or deny care to a patient. ~~should use urine drug testing before starting chronic opioids therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled substances and illicit drugs.~~

Recommendation 11

Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.

The AMA’s 2016 comments remain relevant. Benzodiazepines are a co-occurring substance in a substantial minority of patients who suffer an opioid-related overdose, just as they are commonly used by other individuals as a pattern of polysubstance abuse. Therefore, we recommend that the language be framed in a way that recognizes the clinical decision making authority of the treating physician, to read as follows: **Clinicians should avoid prescribing opioid medication and benzodiazepines concurrently whenever possible, unless it is clinically indicated and required for optimal patient management.**

Recommendation 12

Clinicians 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.

The AMA supports this recommendation and observes that there remain significant structural barriers to care for patients with an opioid use disorder. The ability of primary care physicians to “ensure that patients get treatment for opioid use disorder when needed” is severely constrained by a lack of access to treatment and numerous public and private payer policies that are based on a lack of understanding that addiction is a chronic brain disease. The AMA has fought continuously in state legislatures to remove barriers, including prior authorization for medications to help treat opioid use disorder, but health insurers have been more successful in defeating this effort.

As the Legal Action Center reported last month, less than half the states have removed prior authorization for even one MAT medication.²² Moreover, health insurers have largely gone unchecked in non-compliance with federal and state mental health and substance use disorder parity laws. We are very encouraged that the National Association of Insurance Commissioners is taking meaningful steps to address parity.²³ While we recognize that CDC does not typically play a role in legislative advocacy, there is clearly a role for CDC to make clear that administrative barriers to treatment for opioid use disorder must be removed for the epidemic to end. CDC's affirmative statement in support of removing these barriers would go a long way to help ensure patients receive the care recommended by their physician—and the CDC.

Accordingly, we urge that this recommendation be revised to read as follows:

Clinicians should offer or arrange evidence-based treatment, including medications used to treat opioid use disorder in combination (~~usually opioid agonist treatment in combination with behavioral therapies, where available~~) for patients with opioid use disorder.

In order to achieve this goal, more physicians need to be incentivized to provide direct patient care for individuals with opioid use disorder, and government funding, as well as public and private payer policies, must be fundamentally altered and aligned in support of expanded access to treatment. In addition, efforts should be directed at reducing the stigma associated with substance use disorders and raising awareness that addiction is a chronic brain disease. We encourage CDC to take an active role in supporting reforms at the state and federal levels to achieve these goals.

New recommendation for patients with pain who may have a history of an opioid use disorder

One additional consideration for the revised CDC Guideline is how to effectively manage pain for patients who are suspected of having or have a history of an opioid use disorder or co-occurring substance use disorder. Patients with pain may have co-morbidities that need to be addressed as part of a comprehensive treatment plan. This includes the possibility that they may have a known or undiagnosed substance use disorder.

This is a slightly different consideration than what CDC presents in Recommendation 12 in that CDC can help undo some of the damage from the CDC Guideline by acknowledging how patients with pain can and should receive treatment for their pain even if they have a current or history of an opioid use disorder. By placing so much emphasis on reducing opioid prescribing, the CDC has caused considerable fear in the patient and medical community that opioid therapy for pain will automatically cause opioid use disorder, overdose, and death. This has led to patients sometimes being denied effective pain care in the emergency department, after surgery, and in primary care settings. In some situations, patients also have chosen to forgo opioid therapy after an injury for fear that their history of opioid use disorder would cause them to become dependent on opioids and increase their risk for overdose and death.

²² Spotlight on Legislation Limiting the Use of Prior Authorization for Substance Use Disorder Services and Medications. Legal Action Center and Center on Addiction. May 2020. Available at <https://www.lac.org/resource/spotlight-on-legislation-limiting-the-use-of-prior-authorization-for-substance-use-disorder-services-and-medications>.

²³ See, Mental Health Parity and Addiction Equity Act Workgroup, National Association of Insurance Commissioners. https://content.naic.org/cmte_b_mhpaea_wg.htm.

Deborah Dowell, MD, MPH

June 16, 2020

Page 17

As such, the AMA recommends the following:

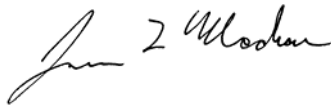
Recommendation 13

Patients with a current or history of an opioid use disorder should receive effective pain care, including opioid therapy when clinically indicated and in consideration of known risks and *benefits*.

The AMA appreciates the opportunity to review and comment on this important issue. We were extremely pleased that CDC last year recognized the misapplication of the CDC Guideline by many stakeholders, and we sincerely hope that CDC will seize the opportunity to revise the CDC Guideline to align with and encourage policy reforms necessary to protect patients with pain.

If you have any questions, please contact Margaret Garikes, Vice President of Federal Affairs, at margaret.garikes@ama-assn.org or 202-789-7409.

Sincerely,

A handwritten signature in black ink, appearing to read "Jim L. Madara". The signature is fluid and cursive, with the first name "Jim" being more prominent.

James L. Madara, MD