# Draft CDC Clinical Practice Guideline for Prescribing Opioids – United States, 2022: Overview of Community Engagement and Public Comment Opportunities

#### Overview

CDC would like to thank all those individuals who participated in the community engagement opportunities and requests for public comment. The feedback obtained through these activities and gathered during BSC/NCIPC meetings was extremely valuable in the process of updating the Guideline, and much of this input is reflected in the document posted for public comment in the Federal Register. Thank you for sharing your experiences with CDC.

The draft *CDC Clinical Practice Guideline for Prescribing Opioids* (draft updated Guideline) will support clinicians as well as patients living with pain and their families, friends, and caregivers. CDC offered several opportunities to gain the perspectives of these groups to help inform the update of the 2016 *CDC Guideline for Prescribing Opioids for Chronic Pain* (2016 Guideline). These activities included (1) soliciting public comments through Federal Register Notices (FRNs) and holding individual conversations about pain management and (2) soliciting public comments through meetings of the Board of Scientific Counselors of the National Center for Injury Prevention and Control (BSC/NCIPC). These efforts are described below, along with themes and findings that emerged from this work.

CDC reviewed thematic summaries of public comments and individual conversations from the FRNs related to pain and pain management to learn more about the values and preferences of patients, caregivers, clinicians, and experts before drafting the updated Guideline. Key themes that emerged from public comment and are reflected in the draft updated Guideline include challenges to patient-provider relationships and the need for patients and providers to make shared decisions; the impact of misapplication of the 2016 Guideline; inconsistent and inequitable access to effective pain management solutions; and reducing opioid use through diverse approaches while ensuring appropriate pain management. Insights gleaned from this effort were shared with the authors drafting the updated Guideline and were integrated into CDC's Guideline revision process. These themes will also be used internally to inform the design of potential dissemination and engagement strategies once the updated Guideline is released. Several examples of where this input is reflected in the draft updated Guideline are included in this report and are meant to provide a brief summary of the inclusion of represented themes. These examples do not represent a comprehensive account of how the draft updated Guideline reflects all submitted public input.

## I. Community Engagement Values and Preferences Federal Register Notices

To better understand the lived experiences and perspectives of community members that we serve, CDC posted two Federal Register Notices (FRNs) to learn more about values and preferences related to pain and pain management options (including but not limited to the benefits and harms of opioid use) to complement ongoing Guideline update efforts. The first FRN solicited input through public comment and the second FRN solicited input through individual conversations.

CDC posted a Request for Written Comment in the Federal Register on April 17, 2020. Comments were accepted from the public through June 16, 2020. CDC invited input on topics focused on using or prescribing opioid pain medications, non-opioid medications, or non-pharmacological treatments (e.g., exercise therapy or cognitive behavioral therapy). In total, CDC received 5,392 comments (on average, more than 88 comments per day), including 4,150 from patients, 431 from caregivers, 109 from healthcare providers, and 702 from advocates or industry groups.

The Lab at the U.S. Office of Personnel Management (OPM) worked with CDC to design and implement community engagement opportunities to gain additional insight into the values and preferences of patients with acute and chronic pain, patients' family members and/or caregivers, and clinicians who care for patients with pain conditions that can complicate pain management (e.g., opioid use disorder or overdose). A human-centered design process was employed to conduct this exploration of community members' experiences and perspectives. Human-centered design is a creative and strategic approach to solving challenging problems (("Human Centered Design (Design Thinking)", n.d.). The method prioritizes people's perspectives at the center of the process. It considers behaviors, diverse thought processes, and people's needs and aspirations. Discovery and design methods offer a sense of why specific people might be experiencing things and provide insights and inspiration to successfully develop interventions. The community engagement was authorized under the Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (OMB Control Number: 0920-1050) approval for the Paperwork Reduction Act.

CDC and OPM held two workshops with staff from CDC and the Centers for Medicare and Medicaid Services (CMS) to plan the community engagement processes. CMS was invited to participate in these workshops due to their own use of the human-centered design process in their activities. Workshop participants included patients, clinicians, Guideline authors, and other subject matter experts. Workshop topics included framing priority needs for public input, objectives for individual conversations, and synthesizing engagement strategies based on insights from public comments and conversations with patients, caregivers, and clinicians.

CDC planned to have individual conversations with patients, caregivers, and clinicians in person but pivoted to holding conversations with individuals in a virtual format due to the COVID-19 pandemic. CDC posted a companion <a href="Federal Register Notice">Federal Register Notice</a> from July 22, 2020 through August 21, 2020 to solicit input and participation from patients, caregivers, and clinicians interested in having individual conversations. After the Federal Register Notice closed, CDC and OPM randomly selected participants\* within each group (i.e., patients, caregivers, clinicians) from a total of 973 people who expressed interest in participating and sharing their pain treatment values and preferences and developed a randomly-selected waitlist of participants.

CDC and OPM conducted telephone and video conversations throughout September 2020 and spoke with 106 individuals, which included 42 patients, 21 caregivers, and 43 clinicians. Participants provided verbal consent for their conversations to be recorded. CDC and OPM reviewed recordings to develop anonymized transcripts and thematic summaries. While discussion guides were used to facilitate conversations with patients, caregivers, and healthcare providers, each participant was also invited to expand upon other topics of importance to them. Topics covered during these conversations included: managing pain, including the benefits, risks, and/or harms of pain management options such as opioid pain medications, non-opioid medications, or non-pharmacological treatments; choosing among the pain management options listed above, including considering factors such as each option's accessibility, cost, benefits, and/or risks; and getting information needed to make pain management decisions.

These conversations included probing questions about how individuals manage pain, choose among the many pain management options, and find information needed to make pain management decisions.

Qualitative, thematic analysis of participants' comments was then performed using manual coding, affinity mapping (organizing concepts and ideas into related clusters), and pattern finding. Within the three dominant themes, there were an assortment of sub-themes, each with supporting insights shared by written comment or direct conversation with participants.

These conversations supplemented what CDC heard from the community during the public comment period and provided more context to what patients, caregivers, and clinicians said. Throughout the conversations, CDC heard many perspectives and personal stories, reinforcing the very nuanced personal and professional experiences of managing and treating chronic and acute pain. CDC and Guideline authors reviewed thematic summaries of public comments and individual conversations to learn more about patients', caregivers', and clinicians' values and preferences. Among the 106 participants in the individual conversations, 45 (42%)

<sup>\*</sup> Participants for these interviews were randomly selected through a random number generator through Microsoft Excel. More information about this function can be found at RAND function (microhttps://support.microsoft.com/en-us/office/rand-function-4cbfa695-8869-4788-8d90-021ea9f5be73soft.com).

reported a perception of being mostly helped by opioids, 33 (31%) reported a perception of being both harmed and helped, 14 (13%) reported a perception of being mostly harmed by opioids, and 14 (13%) had unknown impact.

#### Themes from Community Engagement FRNs

The insights gathered from conversations with patients, their family members/caregivers, and clinicians were combined with the public comments received and analyzed for themes. These themes are described in additional detail below.

Theme 1: Reducing Opioid Use and Ensuring Appropriate Pain Management Through Diverse Approaches

The first theme was reducing opioid use and ensuring appropriate pain management through diverse approaches. Participants noted that effective pain management was essential to helping individuals live full and sustainable lives and should be balanced with an understanding of the known risks presented by opioid therapy. Participants understood the need to reduce unnecessary opioid use and prescribing through varied pain management solutions. They widely supported the assertion that initial pain treatment first should employ non-opioid solutions, including behavioral health interventions to help individuals manage the psychological effects of chronic pain.

Participants generally agreed with the conservative and integrated approach to opioid prescribing outlined in Recommendations 1,  $^{\dagger}$  2,  $^{\ddagger}$  and  $3^{\S}$  in the 2016 Guideline (Dowell, 2016). However, comments repeatedly emphasized that lack of coverage for or access to non-opioid treatments, especially non-pharmacologic therapies, as a first response limits the applicability and utility of these recommendations.

Participants emphasized the need for patients and clinicians to make shared decisions about an individual's care plan, including when opioids are an appropriate course of treatment and when opioid use should be discontinued. To have the full spectrum of pain management solutions available, participants stressed

<sup>&</sup>lt;sup>†</sup> 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 (recommendation category: A, evidence type: 3).

<sup>&</sup>lt;sup>‡</sup> 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 opioid 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 (recommendation category: A, evidence type: 4).

<sup>§</sup> 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 (recommendation category: A, evidence type: 3).

the need for improved access to and coverage of non-opioid and non-pharmacologic therapies and primary care clinician referral to pain management specialists who are trained in advanced diagnostic and pain management planning. Patients cited the variability in access to different pain treatment options and the unique and individualized combination of therapies applied to successfully manage chronic pain to illustrate the personal nature of pain management and to underscore that opioid prescribing guidance should prioritize the discretion of patients and clinicians.

While the FRN invited comments on acute pain, only 6% of comments directly mentioned acute pain. Participant comments about acute pain generally acknowledged value in a conservative approach to prescribing opioids for acute pain based on the risk of misuse but stopped short of advocating for prescribing standards based on procedure. Clinician and advocacy/industry participants noted an opportunity to adjust acute pain management guidance to better align with procedure intensity, while continuing to caution against any guidance that could be interpreted as rigid. Participants observed that acute pain management with opioids seemed to reflect each clinician's or practice's style, comfort level with opioids, and preference, rather than being informed by anticipated levels of pain. Patients' and caregivers' experiential comments added context to this idea. In some anecdotes, participants suggested they were over-prescribed opioids for small procedures, like setting of small bone fractures, where they experienced minimal pain; alternately, some spoke about only having access to over-the-counter pain management following major surgery with long and very painful recovery periods, like open heart surgery.

#### Reflection of Theme 1 in the Draft Updated Guideline

Language included in the introduction of the draft updated Guideline explicitly states that the document is intended to be flexible and enable patient-centered decision-making, taking into account an individual patient's clinical and social circumstances, and should not be applied as inflexible standards of care across patient populations by clinicians, payers, health systems, or governmental jurisdictions. "Implementation Considerations" included under Recommendation #5 indicate that clinicians are strongly encouraged to collaborate with patients to make shared decisions about whether and how to taper opioids.

Recommendations 1 and 2 of the draft updated Guideline note the importance of reducing opioid use through diverse approaches and varied pain management solutions and assert that initial pain treatment first should employ non-opioid solutions, including behavioral health interventions, to help individuals manage the psychological effects of chronic pain:

Recommendation #1: Nonopioid therapies are preferred for many common types of acute pain. Clinicians should only consider opioid therapy for acute pain only if benefits are anticipated to outweigh risks to the patient. (Recommendation Category: A; Evidence Type: 3)

Recommendation #2: Nonopioid therapies are preferred for subacute and chronic pain. Clinicians should only consider initiating opioid therapy if expected benefits for pain and function are anticipated to outweigh risks to the patient. Before starting opioid therapy for subacute or chronic pain, clinicians should discuss with patients known risks and realistic benefits of opioid therapy, should establish treatment goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks. If opioids are used, they should be combined with other therapies as appropriate. (Recommendation Category: A, Evidence Type: 3)

The draft updated Guideline addresses the lack of access and insurer coverage of non-opioid and nonpharmacologic therapies under the "Rationale" under Recommendation #1, which states that, despite a growing body of evidence for their use, noninvasive, nonpharmacologic therapies are not always or fully covered by insurance, which can create cost and access barriers for patients. To improve pain management and reduce medication use and associated risks, health insurers and health systems should work to increase access to these types of therapies.

The draft updated Guideline emphasizes the importance of shared decision-making and individualized patient treatment decisions. The "Implementation Considerations" under Recommendation #2 state that although opioids should not be considered first-line or routine therapy for subacute or chronic pain, that doesn't mean that patients must be required to sequentially "fail" nonpharmacologic and nonopioid pharmacologic therapy or use a specific therapy first before proceeding to opioid therapy. The benefit of opioid therapy in the clinical context should be weighed against the risks before initiating therapy. In some instances, such as contraindications to other therapies, opioids might be the appropriate choice to treat the patient.

The "Background" of the updated Guideline discusses the impact of health disparities among patient populations such as members of racial and ethnic minority groups, women, older persons, persons with cognitive impairment, and individuals with cancer, conditions like sick cell disease, and those at the end of life, all of which can lead to pain that is either undertreated or untreated. Significant issues such as access to nonopioid therapies, referrals to pain specialists, and prescriptions opioids are also described. The role of geography and socioeconomic status in receiving appropriate pain management is also described.

### Theme 2: Impact of Misapplication of the 2016 Guideline

The second theme was the impact of misapplication of the 2016 Guideline. Participants maintained that in some instances, particularly in the management of chronic pain, opioid therapy is the best and/or only appropriate treatment. The 2016 Guideline does not contradict this assessment; however, participants shared

serious concern about how misapplication of the 2016 Guideline by some industries, such as pharmacies and insurers, imposed rigid standards and rules to enforce adherence to those standards. Caregiver and patient comments underscored how misapplication often translated to inconsistent access to effective pain management solutions.

Since the publication of the 2016 Guideline, patients, caregivers, and clinicians noted an increase in clinicians' hesitation to prescribe opioids, reduced dosages, and tapering of prescriptions, which has impacted patient-clinician relationships. Patients and caregivers shared experiences where clinicians refused to continue to care for chronic pain patients utilizing long-term opioid therapies, and the subsequent inability to find new clinicians to provide treatment. Patients and caregivers often described feelings of embarrassment that could arise around these shifts in the patient-clinician relationship. They explained that when a clinician denied opioid treatment, particularly when the patient or caregiver felt it was the only successful way to manage their pain, the denial could elicit feelings of shame or failure. In addition, nearly 15% of all comments included mention of suicide, whether in detailing how unmanaged pain can lead to suicidal thoughts, or how proper pain management with opioid therapy could help to prevent severe outcomes like suicide. Participants shared these details to convey the substantial toll of chronic pain on the lives of individuals and their caregivers. Finally, negative feelings resulting from the 2016 Guideline's misapplication often arose in relation to Recommendation 10.\*\* Patients shared that urine drug testing often seemed randomly or unnecessarily imposed, which made them feel that they were being stigmatized and treated as untrustworthy.

Participants believe that the 2016 Guideline catalyzed a shift away from shared decision-making between patients and clinicians. Many comments, particularly those from patients and clinicians, described instances in which the 2016 Guideline was used by outside industries (e.g., pharmacies, insurance companies, policymakers) in ways that limited the patient-clinician relationship. Each group shared anecdotes and evidence about how misapplication could manifest. For example, participants indicated that pharmacies sometimes used the 2016 Guideline as evidence to support limitations on dosage or refills or refused to fill prescriptions they deem inappropriate. They also noted that their insurance companies took a similar approach, restricting or eliminating coverage for opioids in strict adherence with definitions outlined by the 2016 Guideline. In some instances, this misapplication even arose in policies, whether legislative, regulatory, or institutional, that intended to shape clinicians' scope of practice and enforce punitive action against clinicians who failed to adhere to those policies (Dowell, 2019).

<sup>\*\*</sup> 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.

Caregiver and patient comments underscored how the misapplication of the 2016 Guideline often translated to inconsistent access to effective pain management solutions. They detailed personal experiences with the challenges this created, including diminished capacity due to unmanaged pain, disruptions to daily responsibilities corresponding to both the level of pain intensity, and increased time spent navigating the health care system to access desired care. Caregivers also pointed out that these seemingly minor disruptions and delays to access care could accumulate, becoming significant logistical and financial hurdles.

## Reflection of Theme 2 in Draft Updated Guideline

The "Introduction" includes language noting that the draft updated Guideline provides voluntary clinical guidance and clinical practice recommendations that do not replace clinical judgment and individualized, patient-centered decision-making. The recommendations should not be used as inflexible standards or implemented as absolute limits by organizations, healthcare systems, or jurisdictions. The draft updated guideline is intended to improve communication between clinicians and patients and facilitate important discussions about the risks and benefits of pain treatment, including opioid therapy for pain, as well as improve the safety and effectiveness of pain treatment and reduce the risk of opioid use disorder, overdose, and death, all of which are associated with long-term opioid therapy.

The draft updated Guideline addresses the unique issues and challenges of patients currently on opioid therapy in Recommendation #5:

For patients already receiving higher opioid dosages, clinicians should carefully weigh benefits and risks and exercise care when reducing or continuing opioid dosage. If risks outweigh benefits of continued opioid therapy, clinicians should optimize other therapies and work closely with patients to gradually lower dosages or, if warranted based on the individual clinical circumstances of the patient, to appropriately taper and discontinue opioids (recommendation category: B, evidence type: 4).

The "Implementation Considerations" for Recommendation #5 again emphasize the importance of collaboration between clinicians and patients to make joint decisions about whether and how to taper opioids. Opioid therapy should not be discontinued abruptly and clinicians should not abruptly or rapidly reduce opioid dosages from higher dosages. The discontinuation of long-term, high dose opioid therapy, especially over a short period of time, is associated with adverse events, including overdose mortality. The draft updated Guideline also states that clinicians have a responsibility not to abandon patients and should provide or arrange coordinated management of patients' pain and opioid-related problems. The draft updated Guideline also cites several

studies indicating that both starting and stopping opioids are associated with overdose and suicide risk and notes that discontinuation of opioids over short time periods in particular is associated with greater risks.

The supporting rationale for Recommendation #5 acknowledges that tapering opioids for patients already on long-term opioid therapy can be harmful in some instances. In some instances, the benefits of continuing opioids in these patients might include avoiding the risks of tapering and discontinuing opioids. When the benefits and risks of opioid therapy are considered close, shared decision-making by patients and clinicians is particularly important. Clinicians should not insist on opioid tapering or discontinuation when opioid use might be warranted.

The Guideline should not be used by payers and health systems to set rigid standards related to dose or duration of opioid therapy. Payers and health systems should ensure that cautionary dosage thresholds do not lead to rapid tapers or abrupt discontinuation of opioids, and policies should not penalize clinicians for accepting new patients who are receiving opioids for chronic pain. Patients prescribed opioids but unable to access ongoing care may be at risk for abrupt opioid discontinuation and may miss opportunities to receive life-saving interventions, including monitoring for and management of mental health and substance use issues.

## Theme 3: Environment and Considerations Impacting Reception/Design

During the conversations, a third theme emerged: Environment and considerations impacting reception/design of the Guideline. Providers reported using the Guideline as a tool to educate patients and caregivers and as their first "go to" source for guidance because CDC is seen as trusted and objective. Regarding perceptions, many patients and caregivers described feeling stigmatized by healthcare providers. Patients, caregivers, and providers shared that, for the purposes of pain management, mental health was crucial to assess alongside physical health.

#### Reflection of Theme 3 in Draft Updated Guideline

The draft updated Guideline notes the importance of clinician training, education, and guidance, given the complex array of clinical, psychological, and social consequences associated with pain, such as limitations in activities, reduced quality of life, and pervasive stigma. Clinicians need training, guidance, and resources to provide patients with pain compassionate and appropriate care with a holistic approach.

The issue of stigma is mentioned throughout the draft updated Guideline. The supporting rationale under Recommendation #5 states that many patients "fear stigma, withdrawal symptoms, pain, and/or abandonment (Henry et al., 2019), and it can be helpful to tell patients what to expect (e.g., the rate will be kept slow to minimize withdrawal symptoms; pain may worsen at first but usually improves over time) and that the

clinician will support them through the process."<sup>††</sup> The supporting rationale under Recommendation #10 (toxicology screening) is rated Category B because of concerns about imperfect accuracy, cost, issues with interpretation, and stigma.

## II. Meetings of the Board of Scientific Counselors of the National Center for Injury Prevention and Control

CDC hosted multiple meetings of the Board of Scientific Counselors of the National Center for Injury Prevention and Control (BSC/NCIPC). These meetings were open to the public and announced in advance through notices in the Federal Register. CDC also notified members of the public through the Drug Overdose News<sup>‡‡</sup> email newsletters and email notices to partner organizations. These meetings provided opportunities for spoken public comment and took place on the following dates:

- <u>December 4-5, 2019</u>: CDC provided a <u>background presentation</u> for the draft updated Guideline. At CDC's <u>request</u>, the BSC/NCIPC established the <u>Opioid Workgroup (OWG)</u> to provide independent observations of the draft guideline to the BSC/NCIPC
- <u>July 20, 2020:</u> CDC presented the OWG <u>roster</u> and reviewed the <u>Terms of Reference</u>
- February 16, 2021: Opioid Workgroup Chair provided an update on the status of the OWG
- <u>July 16, 2021:</u> CDC provided an <u>overview</u> of the process and progress for updating the *CDC Guideline for Prescribing Opioids*. The OWG also <u>presented</u> its <u>report</u> on the draft updated Guideline.

Materials from these meetings (including minutes with all written and spoken public comments) are available at <a href="https://www.cdc.gov/injury/bsc/meetings.html">https://www.cdc.gov/injury/bsc/meetings.html</a>.

During the BSC/NCIPC meeting on December 4-5, 2019, CDC provided a background presentation for the draft updated Guideline. At CDC's request, the BSC/NCIPC established the Opioid Workgroup (OWG) to provide independent observations of the draft guideline to the BSC/NCIPC. In addition to BSC/NCIPC members with expertise in pain research or management, CDC announced the process for OWG nominations to the public and followed up after the meeting with notifications via newsletter and emails to partner organizations. CDC identified groups that would be: 1) directly affected by the draft updated Guideline, 2) directly involved with implementing or integrating recommendations into current practice, or 3) qualified to represent a specific discipline or expertise in alignment with the tasks of the workgroup for consideration by the BSC/NCIPC. Identified groups with perspectives that would support the workgroup's capacity included, but were not limited to, patients living with pain, family members and caregivers, clinicians, public health practitioners, and research

<sup>&</sup>lt;sup>††</sup> 103

<sup>&</sup>lt;sup>‡‡</sup> Anyone who would like to receive information related to the ongoing work of the National Center for Injury Prevention and Control (NCIPC), specific to drug overdose prevention (including the ongoing response to the opioid overdose epidemic) as well as other drug overdose updates (e.g., pertaining to resources and tools), may sign up at <a href="https://www.cdc.gov/emailupdates">www.cdc.gov/emailupdates</a> and select topics of interest.

<sup>•</sup> Subscription Topics: Injury, Violence, and Safety

<sup>•</sup> Subtopic: Drug Overdose News

scientists. During this meeting, CDC also heard recommendations from the public and the BSC/NCIPC regarding OWG nominations. CDC received 5 spoken comments and 9 written comments for this meeting.

Individuals were invited to self-nominate by <u>submitting</u> their curriculum vitae and current contact information to <u>NCIPCBSC@cdc.gov</u> on or before Tuesday, February 4, 2020. CDC's BSC/NCIPC received 255 nominations for the OWG. More information about the OWG nomination and selection process is available on the OWG website and in the draft updated Guideline.

CDC presented the OWG <u>roster</u> and reviewed the <u>Terms of Reference</u> at the BSC/NCIPC <u>meeting</u> on July 22, 2020. OWG members included patients with chronic pain, caregivers, and family members of patients with chronic pain. The OWG also included the following perspectives: primary care, pain medicine, public health, behavioral health, pharmacy, emergency medicine, medical toxicology, obstetrics/gynecology, bioethics, orthopedic surgery, plastic surgery, dentistry, sickle cell disease, substance use disorder treatment, and research. Diversity in perspectives was also represented with regard to sex, race/ethnicity, and geographic region. Federal partners served as ex-officio members of the OWG and included representatives from the National Institute on Drug Abuse at the National Institutes of Health, the Substance Abuse and Mental Health Services Administration, the Food and Drug Administration, and the Indian Health Service. The OWG's DFO was a subject matter expert from the National Center for Injury Prevention and Control (NCIPC). In addition to the spoken public comment period held during this meeting, members of the public were invited to submit written comments through July 28, 2020. CDC received a total of 21 spoken comments 88 written comments for this meeting.

Additional <u>updates</u> on the OWG and its activities were provided at the February 16, 2021 BSC/NCIPC <u>meeting</u>, at which CDC received 16 spoken comments and 23 written comments.

At the BSC/NCIPC meeting held on July 16, 2021, CDC provided an <u>overview</u> of the process and progress for updating the *CDC Guideline for Prescribing Opioids*. The OWG also <u>presented</u> its <u>report</u> on the draft updated Guideline. The OWG report was posted in advance of the meeting for the public to review. After the presentations and updates, a public comment period was held. Members of the public could also submit written comments through July 23, 2021. CDC received 39 spoken comments and 479 written comments for this meeting.

#### BSC/NCIPC Meeting: Overview of the Process and Progress for Updating the Guideline and OWG Report

The July 16, 2021, BSC/NCIPC meeting offered an opportunity for the public to provide comments during an extended 2-hour public comment period specific to the presentations given by CDC on the process and progress for updating the Guideline and the OWG's report of the draft updated Guideline. CDC received a total

of 518 public comments: 39 comments during the spoken comment period on July 16, 2021 and 479 written comments by July 23, 2021.

CDC staff reviewed each comment carefully. Comments were organized by theme, commenter, and the subject of the comment itself. The themes identified and used to categorize the comments parallel those used for the public comment FRN and the individual conversations: (1) reduced opioid use through diverse approaches and ensuring appropriate pain management; (2) the impact of misapplication of the 2016 Guideline; and (3) the environment and considerations impacting reception and design of the Guideline.

## Reflection of BSC/NCIPC Meeting Public Comments in Draft Updated Guideline

Throughout the Guideline update process, CDC scientists and staff listened to and reviewed spoken and written public comments from each Guideline related BSC/NCIPC public meeting. All public comments are available in the meeting minutes on the BSC/NCIPC website. Given the details provided at the July 16, 2021 meeting on the process and progress for updating the Guideline, the presentation and discussion of the OWG's report on the initial draft Guideline, the extended 2-hour public comment period, and the large volume of public comments submitted, CDC took additional steps to gain a deeper understanding of both spoken and written public comments associated with this meeting. Comments were organized by audience, overall theme, and the subject of the comment itself. All public comments were provided to the authors for consideration while drafting the updated Guideline.

The majority of comments provided for the July 16, 2021 BSC/NCIPC meeting were provided by patients and pain advocates, including family members and/or caregivers. Other comments were provided by scientific subject matter experts, partner organizations, and industry. The majority of comments were critical of the 2016 Guideline and/or information presented related to the Guideline update, while others were categorized as either neutral or supportive.

	CDC's Response
	For more details, please also refer to the above discussion of
Public Comment Theme from	CDC's response that was related to community engagement
BSC/NCIPC meeting	FRNs.
Reduced opioid use through diverse	CDC added text to re-iterate and emphasize the importance
	•
approaches	of patient preferences and values being understood and used
	to inform clinical decisions and of involving patients in
	decisions about whether to start opioid therapy.
	CDC discusses the issue of access and insurer coverage of
	noninvasive, nonopioid therapies throughout the guideline
	(e.g., "Implementation Considerations" under
	Recommendation 6 and "Conclusion and Future Directions").
	CDC added "Clinical Practice" to the Guideline title and
	throughout the document to reinforce messaging and the
	Guideline's intent.
	CDC added a callout box at the beginning of the revised
	guideline that clearly indicates up front "what the guideline is
	and is not" to help reinforce appropriate guideline
	implementation and prevent potential misapplication.
	CDC added five guiding principles in the "Recommendations"
	section to broadly inform implementation across
	recommendations. In addition, CDC added "Implementation
Impact of Misapplication of the 2016	Considerations" immediately below each recommendation
	statement. These bulleted implementation considerations
	offer practical insights meant to further inform clinician-
	patient decision-making for the respective recommendation
	and are not meant to be rigidly or inflexibly followed.
Guideline	CDC incorporated comments regarding concerns about
	potential misapplication by modifying some recommendation
	statements and moving details within statements to the
	supporting text, where more nuance and discussion was
	included and to avoid the perception of absolute or hard
	limits in some of the bolded recommendations.
	CDC incorporated comments about including specific opioid
	dose thresholds in the recommendations by moving specifics
	from the recommendation statements to "Implementation
	Considerations" in supporting text and adding nuance, where
	appropriate.
	CDC modified text in the "Introduction" and "Rationale"
	(introduction and background section) to further underline
	the guideline's focus on maximizing benefits and minimizing
	risks for individual patients.
Environment and Considerations	CDC discussed the issue of stigma and patients receiving
Impacting Reception/Design	opioid therapy for pain throughout the guideline, including
	the "Introduction" and supporting text of several
	recommendation statements (e.g., Recommendation 5 and
	Recommendation 10).

CDC emphasizes the need for appropriate training for
clinicians treating pain in several places, such as the
"Introduction" and the "Contextual Evidence Review for
Patient and Clinician Values and Preferences and Opioids for
Chronic Pain."

### Conclusion

CDC appreciates and thanks members of the public for their input, insight, and collaboration throughout this important process. We encourage individuals to remain informed about this and other work at the National Center for Injury Prevention and Control's (NCIPC). To receive updates about the Guideline, drug overdose prevention (including the ongoing response to the opioid overdose epidemic), and other drug overdose updates (e.g., pertaining to resources and tools), please go to <a href="https://www.cdc.gov/emailupdates">www.cdc.gov/emailupdates</a> and select topics of interest.

• Subscription Topics: Injury, Violence, and Safety

• Subtopic: Drug Overdose News

#### **Cited Resources**

- 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.rr6501e1external icon.
- 2. Human centered design (DESIGN THINKING). Stanford ChangeLabs. (n.d.). Retrieved September 22, 2021, from https://changelabs.stanford.edu/system-transformation-methodologies-2/design-thinking.
- 3. Dowell, D., Haegerich, T., & Chou, R. (2019). No shortcuts to safer opioid prescribing. *New England Journal of Medicine*, *380*(24), 2285-2287.