



April 11, 2022

Director Rochelle Walensky, MD, MPH
Centers for Disease Control and Prevention (CDC)
National Center for Injury Prevention and Control
Attention: CDC-2022-0024
4470 Buford Highway NE
Atlanta, GA 30341

RE: CDC-2022-0024 – Proposed 2022 CDC Clinical Practice Guideline for Prescribing Opioids, published in Vol. 87 No. 28 (7838-7840) on February 10, 2022.

Submitted electronically via <http://www.regulations.gov>

Director Walensky,

UnityPoint Clinic appreciates this opportunity to provide comments on the Proposed 2022 CDC Clinical Practice Guideline for Prescribing Opioids. UnityPoint Clinic is comprised of more than 1,165 physicians and advanced practice providers in communities throughout Iowa, Illinois, and Wisconsin. UnityPoint Clinic provides services in family medicine, internal medicine, behavioral health, pediatrics, and a wide variety of specialty services, and is the ambulatory arm of UnityPoint Health. UnityPoint Health is one of the nation's most integrated health care systems. Through more than 32,000 employees and our relationships with more than 480 physician clinics, 40 hospitals in urban and rural communities, and 14 home health agencies throughout our 9 regions, UnityPoint Health provides care throughout Iowa, central Illinois and southern Wisconsin. On an annual basis, UnityPoint Health hospitals, clinics and home health provide a full range of coordinated care to patients and families through more than 8.4 million patient visits.

UnityPoint Clinic respectfully offers the following comments.

THEME 1 – PAIN MANAGEMENT THROUGH DIVERSE APPROACHES

The first theme is reducing opioid use and ensuring appropriate pain management through diverse approaches. Significant barriers to opioid alternatives include limited access to or availability of non-opioid medications, adjunct therapies, pain specialists and addiction management. The role of geography and socioeconomic status in obtaining pain management services is also discussed.

Comment: UnityPoint Clinic agrees with an integrated approach to opioid prescribing and management.

This includes access to both opioid and non-opioid treatments. While it's important for providers and patients to make shared decisions about care plans, often non-opioid/non-pharmacological treatments are limited by resource availability or insurer coverage restrictions. For example, a patient may be psychosocially ready for substance abuse services, yet the availability and access to addictive/behavioral

health services is delayed or limited, especially in rural areas. Patients continue to struggle with insurers on coverage of these services, noting in some cases insurers will not pay for cognitive behavioral therapy, acupuncture or massage, and the out-of-pocket expense for physical therapy can be prohibitive for some patients. In addition, non-opioid medications such as Duloxetine and Pregabalin are more effective for some chronic pain conditions and have less potential for abuse, yet frequently they are much more expensive than generic opioids which places them financially out of reach for some patients. Pain management specialists perform injections and other procedures, but most do not provide medication management services. All these factors limit the ability to provide non-opioid/non-pharmacological pain management solutions.

In addressing addiction management, one effective alternative is the use of FDA-approved suboxone (buprenorphine and naloxone). Suboxone is an addiction prevention medication that has proven very safe when used in partnership with addiction specialists. However, the reality is, access is limited to addiction specialists - there are not enough specialists available to evaluate and treat patients with addiction. To further complicate access, providers who manage patients with opioid addiction have faced heightened scrutiny, thus many providers are unwilling to prescribe suboxone due to fear of disciplinary sanctions, including license restriction or revocation. The remaining providers are left to do the best they can with the tools and resources available.

There is no one answer in addressing alternatives to the use of opioid therapies. Successfully managing chronic pain takes a widely accessible integrated care team from primary care providers to behavioral health, specialty providers and adjunct therapies. It takes patient readiness and financially viable coverage. The existing variability of access, readiness, and coverage limits the efficacy of recommendations outlined in the 2022 CDC proposed clinical practice guideline. As an alternative, **UnityPoint Clinic would highly recommend CDC work closely with the Centers for Medicare and Medicaid Services (CMS) in looking for opportunities to implement or increase coverage of cognitive behavioral therapy, non-opioid medications, and adjunct therapies.**

THEME 2 – IMPACT OF MISAPPLICATION OF THE GUIDELINE

The second theme is 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.

Comment: UnityPoint Clinic serves a wide range of patients who have been stable on opioids of varying doses, some for a significant length of time. When a patient has tried and failed alternative therapies and is managed at a dose consistent with clinical guidelines, the goal should not be to taper dosing or find alternative treatment solutions. Patients may not be psychologically or socially ready to effectively manage their pain in a different way. The perception must shift from the reduction of chronic opioid use for all patients to the clinically appropriate management of chronic pain, which may include the continued use of opioids.

Since the issuance of the 2016 guideline, pharmacies, insurers, and policymakers have imposed firm

standards which has led to reduced and inconsistent access to effective pain management solutions. As a result, UnityPoint Clinic has experienced provider hesitancy to prescribe opioids and manage chronic pain. Tenured providers are turning to retirement early and new providers are refusing to prescribe opioids altogether. Providers who remain willing to manage chronic pain find themselves treating more and more patients who are often medically complex with high-risk social determinants of health. The overall impact is that patients struggle to find new providers willing to continue their existing pain management regimen. The denial of opioid therapies or recommendation to lower medication doses leaves many patients with feelings of anxiety, shame, and embarrassment, leading to frequent visits to hospital emergency departments or turning to questionable sources to obtain medications or substances more likely to be counterfeit, contaminated, or illicit, followed by overdose, death, and in some cases, suicide.

Misapplication of the 2016 guideline led policymakers and insurers to enact rigorous standards that had the effect of limiting patients' ability to fill prescribed doses at pharmacies as well as limiting access to certain services and therapies. State administrative rules shaped standards of practice which licensure boards enforced with disciplinary action. This has driven providers to reduce services and practice in the opioid space and has resulted in patients searching for inappropriate pain management solutions outside the walls of the health care institution. The CDC guideline was not intended to create specific standards by which federal or state law is instituted and consequently executed and enforced by professional licensure boards. Additionally, the guideline should not be used by payers and health systems to set rigid standards related to dose or duration of opioid therapy. **It's important to reiterate the drafted guidelines are just that, guidelines to inform and guide treatment decisions. Each patient is unique and as such, providers assess clinical condition, availability of treatment options in the geographic area, and socioeconomic needs, utilizing clinical guidelines as a tool to inform appropriate patient care.** It's imperative we continue to remove the unintended barriers the guideline has rooted into care delivery and continue to support providers in caring for chronic opioid patients without burdensome concern of disciplinary action against them and their professional licensure. **UnityPoint Clinic encourages the CDC to vigorously promote the clinical guideline as a practice tool and discourage its use as a source for restricting the provision of clinically sound, compassionate health care services.**

THEME 3 – Environment and Considerations Impacting Perception/Design

The third theme is using the Guideline as a tool to educate patients and caregivers as their first "go to" source for trusted, objective guidance.

Comment: The guideline recommends toxicology screening including urine drug testing (UDT) to assess compliance with medication use. Not only has this negatively impacted the patient/provider relationship and led to patients feeling stigmatized, but questions have also been raised regarding the accuracy and interpretation of such testing. Further, UDT is often costly and not covered by insurers. While the value of medication compliance is understood, UDT is a significant burden to providers and patients alike, and the drawbacks often outweigh the risks. As such, **UnityPoint Clinic recommends removal of the recommendation of urine drug testing to assess compliance with medication use within the proposed 2022 guideline.**

As it relates to guideline design, **UnityPoint Clinic agrees with the importance of provider training, guidance, and resources to provide compassionate and appropriate care to patients with chronic pain.** Given the complex range of clinical, psychological, and social needs of patients, it is imperative that patients are managed in an environment in which they feel safe, respected, and understood. This requires arming providers with the guidance, knowledge, and tools to proactively engage patients in a variety of pain management options that are appropriate for their individual needs.

We are pleased to provide input on the proposed guideline and the impact on our health care system, our patients, and communities served. To discuss our comments or for additional information on any of the addressed topics, please contact Cathy Simmons, Executive Director, Government & External Affairs at (319) 361-2336 or cathy.simmons@unitypoint.org.

Sincerely,



Dr. Sanjeeb Khatua
President & CEO
UnityPoint Clinic



Dr. Daniel Allen
Chief Medical Officer
UnityPoint Clinic



Cathy Simmons, JD, MPP
Executive Director, Government & External Affairs
UnityPoint Health