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Department of Health
Medical Cannabis Division

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To: Centers for Disease Control and Prevention
From: New Mexico Department of Health on behalf of the State of New Mexico and the Governor's Overdose Prevention and Pain Management Advisory Council

Comments on the Draft Center for Disease Control (CDC) Clinical Practice Guideline for Prescribing Opioids, 2022
Docket # CDC-2022-0024

We applaud the CDC for revising the 2016 pain guidelines and appreciate the opportunity to provide feedback. We understand there is considerable input, and we, as representatives from the State of New Mexico, wanted to put in a single report vetted by the Governor's Advisory Council on Overdose Prevention and Pain Management. The Council is comprised of more than a dozen physicians with diverse backgrounds and specialties (pain management, addiction, chiropractic, acupuncture, dentistry, medical toxicology, emergency medicine, psychiatry, and nonpharmacologic pain management medicine), law enforcement, regulatory bodies (Board of Medicine, Board of Pharmacy, Board of Nursing), Department of Health, Department of Health and Human Services and payers. Additionally, our feedback is supported by our Governor and elected Officials in Washington.

Based on CDC data, peer reviewed publications, data from our home state, and our experience, the overdose epidemic is much worse now than in 2016 (https://www.nmhealth.org/publication/view/marketing/2117/). Considering opioid dispensing was trending down for years before the 2016 guideline, the impact of the 2016 guidelines on improving pain and prevention of inappropriate prescribing is less clear.

New Mexico has had one of the highest rates of overdose deaths for over a decade (https://www.nmhealth.org/data/view/report/2402/ and https://www.nmhealth.org/about/erd/ibeb/sap/dod/) has consistently ranked in the bottom half of opioid prescriptions per 100,000 (https://www.cdc.gov/vitalsigns/painkilleroverdoses/infographic.html).

As a state, New Mexico has learned that simply cutting off the supply of opioids is not sufficient to control pain and overdose mortality. New Mexico has promoted positive collaborative efforts among the justice system, medical system, and behavioral health systems for years, including having state police representation on our governor's council and establishing opioid replacement treatment within correctional facilities. Despite our coordination with law enforcement, we have not been able to influence pharmacy policies absent more clear direction from federal guidance. New Mexico is currently expanding our care for patients who have been on long-term opioids through programs designed to increase access to addiction treatment. While medical practice needs better alternatives for the management of pain, an evidence-based approach to treating substance use disorder (SUD) is critical to addressing the overdose epidemic in the United States.

The comments have been structured with four main points:

- A summary of the report conforming to the word limits of major journals is needed to make the Guidelines more easily understood while highlighting substantial changes.

- Limits or disruption of prescription opioids for pain and substance use disorder are causing negative consequences to patients.

- Legacy patients or patients who have been on opioids longer than three months should be addressed in the CDC guideline.

- CDC should provide a support strategy for appropriate prescribing and dispensing while mitigating supply chain issues; this should include guidance for pharmacies to maintain an adequate supply of both opiates and buprenorphine, reducing issues of delayed access for new patients and disruptions in care for those in continuous treatment.

- Guidance should promote a multidisciplinary approach to pain and pain management.

Executive Summary of Guidelines Needed

It would be very helpful for practicing clinicians if the CDC would include a 2–4-page summary of the guidelines since few clinicians will likely read the guidelines in their entirety. Additional detail in the table of contents would be a practical addition allowing clinicians to find the relevant sections of the guidelines more readily.

As written, the current draft is a detailed, evidenced based review of pain management with a focus on opioids. Although the breadth and detail of the content may serve as a useful reference, it is beyond what most prescribers are willing to read and understand. Additionally, insurance companies, patients, families, nurses, pharmacists, and many others have an interest and want to understand what the CDC is recommending.

Supply-Chain Shortages

Providers and patients in New Mexico have had and are still experiencing barriers to getting timely access to prescribed opioid medications from pharmacies. These problems have resulted in overdose, use of illicit street substances, frustration by patients and clinicians, untreated pain, and uncomfortable withdrawal symptoms. We have been unable to resolve these issues with pharmacies despite years of work and the backing of multiple regulatory boards, the Department of Health, and many clinicians expressing the same concerns.

These problems started shortly after release of the CDC's 2016 guideline. Among the first groups to highlight the problem publicly was the University of New Mexico's (UNM) Pain Clinic. UNM's pain clinic is the only academic pain clinic in the state and maintains an Accreditation Council for Graduate Medical Education (ACGME) accredited pain fellowship. Other pain clinics are experiencing the same problem. In addition to pain clinics, patients on buprenorphine for SUD are also experiencing shortages regularly in practice across the state. In an unpublished survey, aimed at academic boarded addiction medicine providers, all providers reported multiple patients had problems filling their buprenorphine prescriptions. In addiction medicine, patients are evaluated at the end or on the last day of their prescription and those at highest risk of relapse are given a week or less. In the same survey aimed at the academic addiction

providers, providers reported cases of opioid overdose, relapse, use of illicitly sourced substances, worsening of the patient provider relationship, and opioid withdrawal.

To understand the problem and to seek a solution, we sought guidance from the DEA. The DEA indicated that they do not see any barriers to pharmacies maintaining adequate medication supplies and expressed a willingness to talk with pharmacies. The New Mexico Board of Pharmacy has also explained they are fully supportive of patients receiving appropriately prescribed medications for opioid use disorder (MOUD). When the Department of Health Pharmacist approached a chain pharmacy, he was welcomed locally, but told any discussions would need to be with the corporate legal office and no further information about why was given.

Some large chain pharmacies stated they were following the 2016 Guideline or said they were only provided a limited supply and needed to ration. We feel this is unethical to place community pharmacists in the position of deciding who will get their limited supply of opioid pain pills, as they have not performed history and physicals on patients and yet are now being asked to figure out rationing strategies. While we understand medication shortages are commonplace in medicine, these shortages are occurring across the state, with dozens of pharmacies, over years, and commonly when FDA is reporting no shortage. It seems like this is a deliberate choice on the part of the chain pharmacies that has significant negative effects on patients.

The CDC guidelines should include a section for guidance for individual pharmacies and large chains on how to monitor for inappropriate prescribing by physicians and inappropriate dispensing by pharmacies while still maintaining availability of these medications when they are being appropriately prescribed. There should be consequences for pharmacies found to be inappropriately dispensing or physicians who are inappropriately prescribing. Patients found to be diverting, doctor shopping, or other concerning behavior should be screened for SUD and other conditions. If they are found to be selling the medications, there should be consequences for that. However, the current strategy of simply limiting availability of opioid pain pills across the board causes significant harm to patients and has never been shown to be of benefit.

We acknowledge and appreciate in the 2022 guidelines the removal of opioid dosing limits. This could go a long way to influence historical pharmacy and payer policies that introduce significant barriers to access.

Legacy patients/inherited patients

The guidelines must address legacy patients (patients who have been on long-term prescribed opioids for chronic pain) and, for whatever reason, are no longer able to obtain medications from their provider. The last few years have seen many of these patients have their opioids discontinued, often by clinicians or insurance companies mistakenly applying portions of the earlier guidelines to these patients. This has resulted in many tragic outcomes, including overdose, substance use disorder, suicide, leaving many patients with severe, untreated pain, and even health care providers being murdered.

A recent article in the New England Journal of Medicine (Coffin, P., and Barreveld, A. *New England Journal of Medicine*, 2022 https://pubmed.ncbi.nlm.nih.gov/35148038/) outlined some of the issues associated with inherited patients very well. Many of these patients have been on chronic opioids for years, if not decades. These patients must be treated differently, because their long exposure to opioids has caused multiple changes in how their body responds to both pain and to opioids. Improperly applying guidelines intended for patients who are opioid-naive can have devastating outcomes. It is dangerous for an opioid-tolerant patient to abruptly stop opioids. Unfortunately, the data is extremely limited involving legacy patients. In the

consideration of lack of data, it is essential to have expert recommendations. The best approach should involve the patient in the decision making and include developing other treatment programs for control of pain. At a minimum, the CDC should issue recommendations recognizing the harm in abruptly stopping or discontinuing opioids in patients who have been on opioids for several months or years.

Guidelines for addressing this should include the following:

1) Definition of a legacy patient. This should include length of time on opioids, dosage of opioids, and presence of tolerance/physical dependence. The definition should be as broad as possible and include all patients who have been on long-term prescribed opioids for chronic pain and have developed some degree of dependence.

Proposed definition: A legacy patient is a patient who has been prescribed a regular dose of an opioid pain medication by a medical provider for over 3 months.

2) Proper evaluation of a legacy patient.

A. All patients should be evaluated for opioid use disorder.

B. Past work-up for pain should be reviewed. If the work up is incomplete, not documented, or if there are new issues, further workup should be performed.

C. Consider a collaborative care team approach. For example, the team might include pain management, PT/OT, PM&R, acupuncture, chiropractic, mental health for depression and anxiety, and clinical pharmacist.

3) Guidelines for weaning/discontinuation. The guidelines need to include whether every patient should be weaned, and if so, how it should be done. It should also include the risks of weaning pain medications.

A. Clinicians need to discuss possible weaning with every patient and how that decision will be made. The discussion should include the following:

1. The potential risks of high dose opioids, including risk of overdose, risk of opioid use disorder, and sleep apnea. There are also substantial side effects, including constipation and drowsiness.

2. The potential benefits of weaning/discontinuing opioids, including improvement or resolution of opioid-induced hyperalgesia if the patient is on a high dose of opioids and decreased risks of the above side effects.

3. The potential benefits of including non-pharmacological treatments in the opioid weaning schedules including acupuncture (Liu, et. al. *Cellular and Molecular Neurobiology*, 2009 www.ncbi.nlm.nih.gov/pmc/articles/PMC3689320) and chiropractic utilization.

4. The potential risks of weaning, including risk of risk of suicide and overdose (Hallvik et al. *Pain*, 2022 https://psnet.ahrq.gov/issue/patient-outcomes-after-opioid-dose-reduction-among-patients-chronic-opioid-

therapy) and the risk of mental health crisis (Agnoli, A., et al. *JAMA,* 2021 https://pubmed.ncbi.nlm.nih.gov/34342618/).

B. The patient needs to be included in any decision to wean opioids.

C. The risks of tapering are higher with a longer course of opioids (Agnoli et al.).

D. The risks of abrupt withdrawal are worse than gradually discontinuing (Agnoli et al.).

E. A longer time of weaning is associated with fewer adverse events (Mark, T.L., Parish, W. *J Subst Abuse Treat,* 2019 https://psnet.ahrq.gov/issue/opioid-medication-discontinuation-and-risk-adverse-opioid-related-health-care-events).

F. The decision to wean opioids should never be based solely on the patient's MME.

G. The clinician should attempt to maintain a therapeutic relationship with the patient regardless of the decision about weaning. If a therapeutic relationship cannot be maintained, the clinician should offer to assist the patient in finding and transferring care to another provider. The clinician does not need to refer to a provider who will continue opioids if the clinician does not feel it is safe.

4) Guidelines for patients who are found to have opioid use disorder.

A. All patients should be given a prescription for naloxone. This is required by law in New Mexico and many other states if a patient is prescribed opioids.

1. New Mexico requires medical providers educate individuals who are initially prescribed an opioid analgesic on the use of opioid antagonists, such as naloxone, and to provide this education annually to any patient prescribed an opioid analgesic. The medical provider is also required to provide a prescription for an opioid antagonist to any individual who is prescribed five days or more of an opioid analgesic and include written information on administration of the opioid antagonist and information on calling 911 when an opioid antagonist is administered (NMSA 24-2D-7) https://nmonesource.com/nmos/nmsa/en/item/4384/index.do?zoupio-debug#!fragment/zoupio-_Toc79147737/(hash:(chunk:(anchorText:zoupio-_Toc79147737),notesQuery:'',searchQuery:naloxone,searchSortBy:RELEVANCE,tab:search))

2. New Mexico requires individuals released from correctional facilities who have been diagnosed with opioid use disorder be provided with education about opioid use and overdose prevention. The individual is also provided with an opioid antagonist as funding permits, and a prescription for an opioid antagonist (NMSA 33-2-51) https://nmonesource.com/nmos/nmsa/en/item/4396/index.do?zoupio-debug#!fragment/zoupio-_Toc88059602/(hash:(chunk:(anchorText:zoupio-_Toc88059602),notesQuery:'',searchQuery:naloxone,searchSortBy:RELEVANCE,tab:search))

B. If possible, these patients should be transitioned to methadone (OTP), buprenorphine, or naltrexone. The provider should follow guidance from the FDA package insert of DATA 2000 approved course to start a patient on buprenorphine.

C. If buprenorphine or methadone is not available in a patient's community, the clinician needs to weigh the risk of overdose or worsening opioid use disorder with continuation of opioids versus the risk of abrupt discontinuation of opioids, including the increased risk of overdose, as noted above (Mark and Parish, Hallvik et al.). The provider should consider in-patient treatment for patients who are found to be at high risk for overdose. Telehealth options should also be considered. If the decision is made to wean or discontinue opioids, mitigation treatment with non-opioid medications should be used.

D. Risk factors for overdose include being aged 75 years or older, being male, receiving Medicaid or Medicare Advantage coverage, having a comorbid substance use disorder or depression, and having medical comorbidities. Prescription-related risk factors included an initial prescription of oxycodone or tramadol, concurrent use of benzodiazepines and other CNS depressants, and filling opioid prescriptions from 3 or more pharmacies (Weiner, S.G., El Ibrahimi, S,, Hendricks, M.A., et al. *JAMA Netw Open,* 2022 https://pubmed.ncbi.nlm.nih.gov/35089351/).

5) Patients on chronic opioids with poor pain relief

A. Clinicians should ensure that all non-opioid measures are fully utilized.

B. Clinicians should evaluate for and discuss opioid-induced hyperalgesia and that transitioning to buprenorphine (Induru, R.R., Davis, M.P. *Am J Hosp Palliat Care,* 2009 https://pubmed.ncbi.nlm.nih.gov/19666890/) or methadone (Lee M., Silverman S.M., et. al. *Pain Physician*, 2011 https://pubmed.ncbi.nlm.nih.gov/21412369/) or weaning off opioid medications may improve patient's pain. Methadone and buprenorphine are more effective for pain when dosed 3-4 times daily. Methadone should not be used to treat acute pain, as it has a long duration of action. Methadone can be slowly titrated up. If a clinician suspects opioid use disorder, they should not prescribe methadone outside of a methadone clinic.

6) Adjunctive treatment

A. Providers should encourage adjuvant treatments discussed in the earlier CDC guideline. However, if a patient feels they are getting good relief from their current regimen, opioids should not be discontinued if patients decline other medications.

7) What should a provider do about concurrent use of risky medications with opioids, including benzodiazepines, illicit opioids, alcohol, and other illicit substances?

A. Patients on prescribed benzodiazepines should be encouraged to wean either the benzodiazepine or the opioid.

B. Patients using illicit substances need to be closely evaluated for substance use disorder and risk of overdose. Clinicians should consider changing to buprenorphine or referring for methadone if appropriate.

8) Recommendations of treatment of acute pain/procedural pain in patients on long-term opioids

Telehealth

There are major challenges in access to expert care among minorities and those in rural regions. The CDC guideline should address increasing access to expertise for both pain and SUD's while emphasizing underserved populations. While we prefer local clinicians who the patients may interact with, they may not have the training and expertise. Telehealth has been shown as an effective means of connecting experts with patients in underserved areas.

The only references to telehealth in the proposed guidelines are:

On page 120, #7 "Clinicians should evaluate...", under "Implementation Considerations" on page 121 (and again on 123) it states, "In practice contexts where virtual visits are part of standard care (e.g., in remote areas where distance or other context makes follow-up visits challenging), follow-up assessments that allow the clinician to communicate with and observe the patient through telehealth modalities may be conducted."

On page 166, within the section "The areas in need of additional research include but are not limited to" includes this comment "Effective management of patients on high dose opioids: the application of multidisciplinary and multimodal models of pain treatment, and service delivery modalities including telehealth."

We recognize the intention behind the Ryan Haight Act of 2008 which requires an in-person meeting with a patient before the provider can prescribe a controlled substance for the treatment of pain or for treating OUD, but also found its limitations to hinder effective care as New Mexico is primarily designated as "rural" or "frontier", with the challenges associated with service access in those regions. Telehealth services are critical to managing people's healthcare.

We believe that there should be exceptions [1] to the Ryan Haight Act available to providers treating pain, SUD, and related complications from treatments detailed in this CDC guideline allowing underserved populations similar health care opportunities using telehealth as the general population. This could entail an initial evaluation using a mobile unit or telehealth visit when a mobile unit is not available. At minimum, patients should be able to consult remotely with pain and addiction providers from their local physician's office.

Additional guidance from the CDC in support of the March 23, 2022, DEA announcement that they are making permanent the COVID telehealth exceptions to Ryan Haight for OUD treatment might encourage more MOUD telehealth prescribing by primary care providers in resource scarce communities. Additional suggestions, perhaps under the "Areas in need of additional research" would be encouragement for the DEA to consider exceptions and regulations that would allow telehealth options for the initial prescribing of controlled substances for purposes other than OUD. See below for the recent announcement from the DEA:
https://www.dea.gov/press-releases/2022/03/23/deas-commitment-expanding-access-medication-assisted-treatment

https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202110&RIN=1117-AB40

https://www.deadiversion.usdoj.gov/fed_regs/rules/2009/fr0406.pdf (Page 9 (15603))

Non-pharmacological pain management

Over the last several decades, scores of studies have reviewed non medication treatment to manage chronic pain. While most are familiar with physical therapy, occupation therapy, decades of literature demonstrating safety in efficacy with mental health, acupuncture, chiropractors, and massage exists. These areas have dozens of randomized control trials evaluating the safety and efficacy. We believe the CDC should include a section on these minimally invasive therapies and recommend that patients should have the option to be referred. Given the wealth of information, we will focus on the published meta-analysis and professional medical societies.

Behavioral interventions

Also, we recommend explicit inclusion of behavioral interventions in the recommendations. Cognitive behavioral therapy, acceptance and commitment therapy, and mindfulness-based programs have well-documented effectiveness for the treatment of chronic nonmalignant pain. Integration of such behavioral health therapies into primary care settings may optimize health resources and improve treatment outcomes. We recognize the comorbidity of depression, anxiety, post-traumatic stress disorder (PTSD) and other mental health diagnoses are nearly universally present in patients with chronic pain (Majeed, M. H., Ali, A. A., & Sudak, D. M. *The International Journal of Psychiatry in Medicine,* 2019 https://doi.org/10.1177/0091217418791447).

Integrative Treatments: Acupuncture and Chiropractic Medicine

According to the American College of Physicians Practice Guidelines on Noninvasive Treatments: Acute and subacute low back pain often resolve spontaneously; however superficial heat, massage, acupuncture, and spinal manipulation are good initial treatment options. There have been few harms reported with these treatments, and those that occur are not severe. For chronic low back pain, exercise, multidisciplinary rehabilitation, acupuncture, mindfulness-based stress reduction, tai chi, yoga, motor control exercises, progressive relaxation, electromyography biofeedback training, low-level laser therapy, operant therapy, cognitive behavior therapy, and spinal manipulation are first-line options and have fewer harms compared with medication; therefore, they should be tried initially (Hauk, L. *Am Fam Physician*, 2017 https://www.aafp.org/afp/2017/0915/p407.html).

There are dozens of systematic reviews with meta-analysis that have reviewed randomized control trials of acupuncture. There is strong agreement in the literature in support of acupuncture for subacute and chronic back pain, migraine prevention, and stress or tension headaches.

Washington State's Medicaid program, known as Apple Health, has an administrative body known as its Health Care Authority (HCA). In 2020, their HCA published a paper called Apple Health Nonpharmacologic Pain Treatment Coverage in which they studied information about the utility and cost-effectiveness of acupuncture, chiropractic, and massage therapy as nonpharmacologic pain treatments. They concluded that acupuncture has evidence of treatment effectiveness, is sufficiently cost-effective, and is the least costly treatment to provide, based on expected utilization. Because of this study, they requested approval from the Centers for Medicare and Medicaid Services (CMS) to add acupuncture and chiropractic benefits for adult Apple Health coverage in the state plan amendment (SPA):

https://www.hca.wa.gov/assets/program/apple-health-nonpharmacologic-pain-treatment-coverage-20200110.pdf.

One meta-analysis addressed the efficacy of acupuncture when combined with allopathic therapies. Withdrawal-symptom scores were lower in combined acupuncture plus opioid agonist (weaning) treatment trials than in agonist-alone trials on withdrawal days 1, 7, 9, and 10. Combined treatment also produced lower reported rates of side effects and appeared to lower the required dose of opioid agonist. This meta-analysis together with anecdotal experience from multiple acupuncturists' own practice, suggests that acupuncture combined with opioid agonists can effectively be used to manage multiple withdrawal symptoms which prevent so many patients from successfully transitioning to opioid discontinuation (Liu, et. al. *Cellular and Molecular Neurobiology*, 2009 www.ncbi.nlm.nih.gov/pmc/articles/PMC3689320).

The American College of Physicians Low Back Pain Treatment Guideline includes the use of nonpharmacologic therapies (Qaseem et al. *Annals of Internal Medicine*, 2017 https://www.acpjournals.org/doi/10.7326/M16-2367) as successful pain medication treatment. Additionally, meta-analysis from 2020 assessing chiropractic medicine and opioid use, showed significant reduction in opioid utilization. Patients receiving care from a chiropractic physician for lower back or neck pain have a 64% lower chance of receiving an opioid prescription. This article, in addition to numerous cohort and observational studies that have been published since 2020, suggest chiropractic medicine is an efficient way to reduce harm from opioid pharmacology (Corcoran, et. al. *Pain Medicine*, 2020 https://pubmed.ncbi.nlm.nih.gov/31560777/).

Given the current literature, the CDC's published guidelines highlight the inclusion of acupuncture and chiropractic medicine as a generally safe, evidence-based, cost-effective, nonpharmacologic treatment. For both primary prevention, to reduce/prevent need for opioid medication therapy in the first place; and secondary prevention, to reduce need for amount of ongoing opioid medication therapy and/or assist weaning schedules of opioid agonist medication(s). All while preventing opioid overdose and promoting safer nonpharmacologic pain management.

The State of New Mexico appreciates the opportunity to comment on these draft guidelines and the efforts the CDC has made to improve opioid prescribing and pain management with respect to opioid prescribing practices. If you have questions regarding our comments or need additional information, please contact me at Dominick.Zurlo@state.nm.us

Sincerely,

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