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November 11, 2023

The Honorable Xavier Becerra, Secretary
U.S. Department of Health and Human Services
Melanie Fontes Rainer, Director
Office for Civil Rights
U.S. Department of Health and Human Services
Attention: Disability NPRM, RIN 0945–AA15
Hubert H. Humphrey Building
Room 509F, 200 Independence Avenue SW
Washington, DC 20201

re: **RIN 0945–AA15** Proposed Rule Updating and Amending Regulation under section 504 of the Rehabilitation Act of 1973 (section 504), 88 FR 63392.

Dear Secretary Becerra and Director Rainer:

The National Pain Advocacy Center (NPAC) writes in support of the Department's proposed updates and amendments to its section 504 regulation implementing the prohibition of discrimination on the basis of disability and to offer specific feedback on its expanded sections on medical treatment and values assessment.

NPAC is a 501(c)(3) nonprofit alliance of clinicians, scientists, public health experts, and people with lived experience, advancing the health and human rights of people living with pain. We envision a world in which pain is treated equitably and effectively. NPAC includes experts in pain and addiction, people with lived experience of pain, and people in recovery from addiction.

We write primarily to request that the Department further emphasize the central role individualized inquiry plays in medical treatment decisions when it issues a final rule. In response to the Department's request for examples of discrimination, we illustrate the need for individualized inquiry with the example of discrimination against people with pain.

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Medical Treatment

We appreciate the explicit recognition in the proposed updates that section 504 governs not simply access to care but also medical decision-making based on generalizations or stereotypes about disability. We believe that the proposed regulation appropriately applies the standards articulated in *Bragdon v. Abbott* and *Bowen v. University Hospital* and that the Department's analysis will be useful in ensuring appropriate, individualized, nondiscriminatory medical care of individuals with disabilities.

1. *Pain and Disability*

Persistent pain is the chief cause of long-term disability globally and in the U.S. More than 50 million Americans experience pain every day or nearly every day of their lives and between 17 and 20 million have "high-impact" pain, or pain that regularly impedes life activities and work. The number of Americans who would meet the definition of disability under Section 504 reaches beyond those with high-impact pain but would not likely include all 50 million. Regardless, pain represents a significant disability cohort.

There are many ways of treating pain, but for some people with persistent pain, opioids are an appropriate and essential medication. Approximately 8 million Americans use opioids to manage it. For reference, this represents approximately three times the number of people with an opioid use disorder. All current guidelines including those issued by the Centers for Disease Control and Prevention continue to provide a role for opioids for chronic pain not managed by other means. Yet people with chronic pain who use opioids are experiencing widespread and systemic discrimination in care. This discrimination takes two forms: barriers to accessing care and discriminatory treatment decisions that numerous studies show risk significant harm.

2. *Barriers to Access to Care*

Healthcare providers are increasingly unwilling to treat people with disabilities who use opioids to manage pain. Concurrent studies from the University of Michigan, for example, found pain patients who use opioids can't get into the door at half of primary care clinics in the U.S. (The original study followed clinics in Michigan (Lagisetty, JAMA Netw. Open 2019). A follow-up included 9 states (Lagisetty, PAIN 2021).

The refusal to treat a person based on their disability or the medication they take for that disability is potentially discriminatory under the

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Americans with Disabilities Act and, by extension, section 504. This situation is roughly analogous to those presented in the U.S. Department of Justice's settlements in primary care settings and skilled nursing facilities in which patients with an opioid use disorder who use the opioid, buprenorphine, to manage their disabilities were denied access to care because of the medication they use to treat their conditions.

3. *Discriminatory Treatment Decisions*

A second type of discrimination occurs in medical treatment decisions in which people who take opioids to manage pain—and, in many cases, have been stable on them for decades—are subjected to dangerous opioid cessation or reduction practices that numerous studies show risk their health and lives.

For example:

- One study found just changing a patient's dose resulted in a three-fold increased risk of overdose death. (Glanz, JAMA Netw. Open 2019).
- A study of Medicaid patients on opioids for more than 90 days found discontinuation often happened abruptly with almost half of such cases resulting in hospitalization or an ER visit (Mark, J Subst. Abuse Treat. 2019).
- Tapering in primary care settings is associated with an increased risk of death (James, J Gen Intern Med 2019).
- Veterans who were tapered experience a higher risk of death from overdose or suicide (Oliva, BMJ 2020).
- Opioid tapering is associated with termination of healthcare relationships (Perez, J Gen Intern Med 2020).
- Discontinuation of opioids in patients stable on opioids is on the rise and often happens abruptly (Neprash, J Gen Intern Med 2021).
- Dosage reduction is associated with mental health crises and overdose events. (Agnoli, JAMA 2021).
- The heightened incidence of overdose and mental health crisis from tapering continued two years post-taper. (Fenton, JAMA Netw. Open 2022).
- There is heightened risk of overdose and suicide in patients with no prior use disorder or risk of opioid misuse and these risks occur regardless of the pace of tapering. (Larochelle, JAMA Netw. Open 2022).
- Tapering is associated with an increase in emergency department visits and hospitalizations, fewer primary care visits,

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and lower medication adherence for other chronic conditions (diabetes, hypertension). (Magnan, JAMA Netw. Open 2023).
- Going from over 90 morphine milligram equivalents (MME) to 0-29 within 30 days was associated with a four-fold increased risk of overdose death. (Henry, J Gen Intern Med 2023).

How tapering is done matters.

- The largest study of voluntary tapering shows that where there is patient buy-in and readiness to taper, and patients are permitted to go back up if they experience issues, most patients reduce their dose (although not all, so individualization continues to matter). (Darnall, JAMA Intern Med. May 2018).
- *See generally, HHS Guideline for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics.*

Thus, while a dose reduction or discontinuation may be deemed appropriate where an individualized inquiry has been conducted, what is inappropriate and likely discriminatory are one-size-fits-all policies that compel healthcare providers to discontinue opioids in all patients or to taper everyone to a preset dose threshold regardless of their medical condition or needs. Policies by pharmacy chains or pharmacy benefit plans that require pharmacists to refuse to fill opioid prescriptions or prescriptions over a preset dose threshold – in the absence of any inquiry – are similarly problematic.

A recently enacted law in Colorado provides a good example of appropriate line drawing in addressing this issue: it permits individualized medical discretion but prohibits one-size-fits-all policies that require tapering or refusing prescription fills across all patients.

4. *A Human Example: Kenneth Maestas*

With pain medication, 59-year-old Kenneth Maestas, a Latino man with quadriplegia, lived a full life. He raised his son as a single father, managed a Walmart store, worked as the legislative policy director for the Colorado Cross-Disability Coalition, and contributed to his rural Colorado community.

In August 2019, Kenny saw a new provider because his regular doctor had left the practice. The new provider abruptly discontinued Kenny's opioid medication: Kenny went from taking 30 milligrams of oxycodone three times a day to 0. Kenny fared poorly with abrupt opioid cessation, so much so that his son began spending the night in his father's room to watch over him. And it's a good thing he did. When Kenny's breathing

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became extremely labored, his son called 9-1-1. Kenny flatlined on the table at the hospital. He woke on a ventilator, and in the process suffered significant pressure sores that took months to recover from.

Kenny's story is not unusual. Medically inappropriate, policy-based tapering risks endangering the lives of disabled people with pain. Barriers to accessing care also often result in abrupt opioid cessation. If a person who uses opioids to manage pain loses access to their regular provider and is unable to secure a new one, *de facto* opioid cessation occurs, risking destabilization of their health, mental health, and lives.

5. Summary

A significant driver of the barriers people with pain currently face was the widespread misinterpretation and misapplication of dose and supply thresholds in the CDC's 2016 Guideline for Prescribing Opioids for Chronic Pain. In 2019, the CDC publicly acknowledged this misapplication of its Guideline by policymakers as an unintended consequence, and warned that it risked patient harm. The Food and Drug Administration concurrently issued a warning about dangers associated with opioid cessation and tapering. In 2022, the CDC updated its prescribing guidelines, removing day and dosage thresholds from its topline recommendations.

Despite these changes at the agency level, people with pain continue to face significant barriers in medical treatment. These barriers result from one-size-fits-all policies that are a misapplication of federal policy, which means they are not evidence-based, rely on generalization and stereotypes, and can do substantial harm. As across-the-board policies, they contravene section 504's call for individualized inquiry and assessment.

In sum, we request the Department to elaborate on and underscore the central role individualized inquiry plays in medical treatment decisions ideally using the illustration of widespread and systemic discrimination against people with pain. Doing so would go a long way to protect their imperiled health and lives.

Values Assessment

In addition to the section on medical treatment, we consider the values assessment section an important addition to the section 504 regulation in view of the persistent discrimination that arises from an inappropriate valuation of the lives of people with disabilities. Given the history and persistent use of quality-of-life measures, most recently evinced in the

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inclusion of such measures in state crisis standards of care, the Department's elucidation is critical. We believe that the proposed regulation does a good job of line drawing – leaving open the potential need for scholarship but prohibiting valuations that are, in practice, tantamount to discrimination.

We thank you for your consideration and for the opportunity to respond to this thorough and thoughtful proposed update to the regulations prohibiting discrimination on the basis of disability under section 504.

Warm regards,

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