October 3, 2022

The Honorable Xavier Becerra

Secretary of Health and Human Services

200 Independence Avenue, SW.
Washington, DC 20201

Re: Docket No. HHS-OS-2022-0012, RIN 0945-AA17

Dear Mr. Secretary:

We write in regard to the Department of Health and Human Services’ proposed rule pursuant to Section 1557 of the Affordable Care Act (ACA), Nondiscrimination in Health Programs and Activities, Docket No. HHS-OS-2022-0012, RIN 0945-AA17.

The **National Pain Advocacy Center (NPAC)** is a 501(c)(3) nonprofit alliance of clinicians, scientists, public health experts, and people with lived experience of pain, working to advance the health and human rights of people living with pain. We envision a world in which pain is treated equitably and effectively, so that all people living with pain have the opportunity to live full and productive lives. We are also a race, gender, LGBTQIA+, and disability diverse organization that was formed with a strict ethics pledge to take no pharmaceutical or medical device industry funding.

As an organization dedicated to protecting rights and ensuring equitable care, we applaud the Department’s encyclopedic recitation and digestion of studies showing bias, inequity, disparities and discrimination in health care. As a pain-focused organization, we also appreciate the Department’s discussion of studies demonstrating bias in pain assessment and treatment on the bases of race, gender, and age.

We write to address two items in regard to **section 92.210, Use of Clinical Algorithms in Decision-Making**, specifically: (1) prognostic algorithms, such as SOFA and mSOFA, that are commonly used in state Crisis Standards of Care, and (2) an algorithm known as NarxCare that is increasingly being applied to people living with pain.

We note that algorithms that expressly single out members of disadvantaged groups are inherently problematic, being overtly discriminatory in their disparate treatment of certain groups. Nevertheless, those algorithms that are facially-neutral, but which will have a disparate impact on care through their tendency to screen out members of certain groups, are likely to be especially consequential.

1. ***Algorithms in Crisis Standard of Care.***

The Department has highlighted an emerging body of research showing that SOFA and other prognostic scoring algorithms used in the Crisis Standards of Care frequently overestimate Black mortality, which would result in de-prioritization in their access to healthcare. Pursuant to the Department’s request for recommendations and comments on potential remedies to these algorithms, we reference a law review article co-authored by our Executive Director and Professor Deborah Hellman of the University of Virginia School of Law entitled, *Rationing and Disability: The Civil Rights and Wrongs of State Clinical Triage Programs.[[1]](#footnote-1)*

The article focuses on the disparate impact on people with disabilities and members of racial minorities of the predictive algorithms in state Crisis Standards of Care. It concludes with a novel proposal for modifying these algorithms to redress discrimination and de-prioritization. Specifically, the article proposes the idea of employing “reserve system;” that is, an easy-to-apply algorithm that reserves a portion of health resources for disadvantaged groups that are de-prioritized, in order to ensure a fair allocation of health resources.[[2]](#footnote-2) Using a reserve system would better balance the goal of saving the most lives with that of fairly distributing care, so that individuals with disabilities and members of racial minorities are not unfairly left out.

1. ***NarxCare Algorithms.***

All 50 states and the District of Columbia currently maintain Prescription Drug Monitoring Programs (PDMPS), databases that log prescriptions for controlled medication in real time. A private company, Bamboo Health (formerly Apriss), dominates the management of these databases and has merged them to be interoperable nationally.

NarxCare is Bamboo Health’s predictive algorithm: it mines PDMP data in order to determine a patient’s risk for prescription drug misuse, diversion, and overdose. Each patient is assigned a series of three digit “risk scores” based on factors related to their history of prescription drug use.

While the algorithm is black box and proprietary, it appears to employ proxies, such as the intensity of a patient’s use of medical resources or how far a patient travels to see a provider, in an attempt to screen out “doctor shopping,” a practice in which patients see multiple providers to obtain drugs for misuse. Employing factors like the intensity of use of medical resources may simply screen out the sickest patients, however. Similarly, distance traveled may flag rural patients who must travel to cities to see specialists. In other words, in each case, there may be benign reasons for the flag that do not necessarily increase a patient’s risk of misuse.

Indeed, both in-depth investigative reporting and scholarly research indicates that Narxcare, as a predictive algorithm, very likely artificially inflates the risk scores of many vulnerable groups, including: people with cancer or those with other progressive or co-morbid chronic health conditions, who are mis-identified as “doctor shoppers;” women (even though men are statistically more likely to develop use disorders); members of racial minorities; people who are poor, uninsured, or under-insured; and people living in rural areas.[[3]](#footnote-3)

This artificial inflation of risk scores in vulnerable populations is problematic, because Narxcare scores have led to the denial of care.[[4]](#footnote-4)

Studies suggest that 8[[5]](#footnote-5) to 13[[6]](#footnote-6) million Americans use opioids long-term to manage pain. Although prescribing has dropped in recent years, so the numbers may have declined somewhat, the Narxcare algorithm still stands to affect a significant cohort of people.

Persons who use opioids to manage pain are especially vulnerable to the loss of healthcare today. Studies suggest, for example, that nearly half of primary care clinics in the US will not take on a new patient who uses opioids to manage pain,[[7]](#footnote-7) and that 81% of providers are reluctant to treat such patients.[[8]](#footnote-8)

Moreover, people whom the healthcare system has placed on opioids long term are increasingly being subjected to dangerous opioid cessation practices—in the name of their safety—that studies now show actually increase their risk of overdose and suicide by three to five fold, in addition to destabilizing their health, mental health, and lives.[[9]](#footnote-9)

Given the proprietary character of Bamboo Health’s algorithm and the company’s lack of transparency about the factors it incorporates, the American Medical Association’s framework for “augmented intelligence systems,” mentioned in this proposed rule, is especially useful. In particular, we endorse the conclusion that “providers should understand enough about the tools they are using to evaluate, select, and implement them, and should forgo the use of such tools if the provider does not adequately understand how they work.”

We thank you for the opportunity to comment on this well-considered proposed rule.

Sincerely,

Kate M. Nicholson

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1. ##  78 Wash. & Lee L. Rev. 1207 (2021), https://scholarlycommons.law.wlu.edu/cgi/viewcontent.cgi?article=4741&context=wlulr.

 [↑](#footnote-ref-1)
2. *Id.* at 1276 -1279 (citing PARAG A. PATHAK ET AL., FAIR ALLOCATION OF VACCINES, VENTILATORS, AND ANTIVIRAL TREATMENTS: LEAVING NO ETHICAL VALUE BEHIND IN HEALTH CARE RATIONING 37 (2021), perma.cc/T4UE-5VDF (PDF) (promoting a reserve system because it “offers additional flexibility to balance competing objectives” at n. 268). [↑](#footnote-ref-2)
3. *See*, *e.g.,* Oliva, J., Dosing Discrimination: Regulating PDMP Risk Scores, 110 California Law Review 47 (2022), <https://www.californialawreview.org/print/dosing-discrimination-regulating-pdmp-risk-scores%EF%BF%BC/> (In full disclosure, Professor Oliva is one of National Pain Advocacy Center’s Science and Policy Council advisors); Maia Szalavitz, *The Pain Was Unbearable. So Why Did Doctors Turn Her Away?, WIRED,* August 11, 2021, <https://cssh.northeastern.edu/economics/2021/08/11/the-pain-was-unbearable-so-why-did-doctors-turn-her-away/> (last accessed October 1, 2022). [↑](#footnote-ref-3)
4. *Id.* [↑](#footnote-ref-4)
5. Kroenke, K, Alford, P, Argoff, C, *et al.*, Challenges with Implementing the Centers for Disease Control and Prevention Opioid Guideline: A Consensus Panel Report, *Pain Medicine*, Volume 20, Issue 4, April 2019, Pages 724–735, [doi.org/10.1093/pm/pny307](https://doi.org/10.1093/pm/pny307). [↑](#footnote-ref-5)
6. Mojtabai R. National trends in long-term use of prescription opioids. Pharmacoepidemiol Drug Saf. 2018 May;27(5):526-534. doi.org/10.1002/pds.4278. Epub 2017 Sep 6. PMID: 28879660. [↑](#footnote-ref-6)
7. #  *See* IHPI News, Patients who take opioids for pain can’t get in the door at more than half of primary care clinics, January 25, 2021, <https://ihpi.umich.edu/news/patients-who-take-opioids-pain-cant-get-door-more-half-primary-care-clinics> (last accessed October 1) (citing two studies, Lagisetty, P, Macleod, C,; Thomas, J., *et al.*, Assessing reasons for decreased primary care access for individuals on prescribed opioids: an audit study. PAIN: May 2021 - Volume 162 - Issue 5 - p 1379-1386 doi: 10.1097/j.pain.0000000000002145; Lagisetty P, Healy N, Garpestad C, *et al.*, Access to Primary Care Clinics for Patients With Chronic Pain Receiving Opioids. *JAMA Netw Open.* 2019;2(7):e196928. doi:10.1001/jamanetworkopen.2019.6928.

 [↑](#footnote-ref-7)
8. *See* Quest Diagnostics, Health Trends, Drug Misuse in America 2019, Physician Perspectives and Diagnostic Insights on the Evolving Drug Crisis, <https://mma.prnewswire.com/media/1011170/Quest_Diagnostics___Health_Trends_Report.pdf?p=original> (last accessed October 1, 2022). [↑](#footnote-ref-8)
9. *See e.g*., Mark T, Parish W., Opioid medication discontinuation and risk of adverse opioid-related health care events. J Subst Abuse Treat. 2019 Aug;103:58-63. doi: 10.1016/j.jsat.2019.05.001. Epub 2019 May 5. PMID: 31079950; Glanz J, Binswanger I, Shetterly S, *et al.*, Association Between Opioid Dose Variability and Opioid Overdose Among Adults Prescribed Long-term Opioid Therapy. *JAMA Netw Open.* 2019;2(4):e192613. doi:10.1001/jamanetworkopen.2019.2613; James J, Scott J, Klein J, *et al.*, Mortality After Discontinuation of Primary Care-Based Chronic Opioid Therapy for Pain: a Retrospective Cohort Study. J Gen Intern Med. 2019 Dec;34(12):2749-2755. doi: 10.1007/s11606-019-05301-2. Epub 2019 Aug 29. PMID: 31468341; PMCID: PMC6854174; Fenton J, Agnoli A, Xing G, *et al*., Trends and Rapidity of Dose Tapering Among Patients Prescribed Long-term Opioid Therapy, 2008-2017. *JAMA Netw Open.* 2019;2(11):e1916271. doi:10.1001/jamanetworkopen.2019.16271; Oliva E, Bowe T, Manhapra A, *et al.* Associations between stopping prescriptions for opioids, length of opioid treatment, and overdose or suicide deaths in US veterans: observational evaluation *BMJ* 2020; 368 :m283 doi:10.1136/bmj.m283; Neprash H., Gaye, M, Barnett, Abrupt Discontinuation of Long-Term Opioid Therapy among Medicare Beneficiaries 2012-2017, J. Int. Med. 36(6): 1576-83 2021 <https://doi.org/10.1007/s11606-020-06402-z>; Perez H., Buonora M, Cunningham C, *et al.,* Opioid Taper Is Associated with Subsequent Termination of Care: a Retrospective Cohort Study. J Gen Intern Med. 2020 Jan;35(1):36-42. doi: 10.1007/s11606-019-05227-9. Epub 2019 Aug 19. PMID: 31428983; PMCID: PMC6957663; Hallvik S, El Ibrahimi S, Johnston K, *et al.*, Patient outcomes after opioid dose reduction among patients with chronic opioid therapy. Pain. 2022 Jan 1;163(1):83-90. doi: 10.1097/j.pain.0000000000002298. Erratum in: Pain. 2022 Apr 1;163(4):e613. PMID: 33863865; PMCID: PMC8494834; Agnoli A, Xing G, Tancredi D, *et al.* Association of Dose Tapering With Overdose or Mental Health Crisis Among Patients Prescribed Long-term Opioids. *JAMA.* 2021;326(5):411–419. doi:10.1001/jama.2021.11013; Fenton J, Magnan E, Tseregounis I, *et al*., Long-term Risk of Overdose or Mental Health Crisis After Opioid Dose Tapering. *JAMA Netw Open.* 2022;5(6):e2216726. doi:10.1001/jamanetworkopen.2022.16726; Larochelle M, Lodi S, Yan S, *et al.,* Comparative Effectiveness of Opioid Tapering or Abrupt Discontinuation vs No Dosage Change for Opioid Overdose or Suicide for Patients Receiving Stable Long-term Opioid Therapy. *JAMA Netw Open.* 2022;5(8):e2226523. doi:10.1001/jamanetworkopen.2022.26523. [↑](#footnote-ref-9)