DISABILITY DISCRIMINATION BY CLINICAL ALGORITHM*

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In response to America's escalating drug poisoning crisis, the federal government has funded, incentivized, and mandated that states adopt and implement prescription drug monitoring programs ("PDMPs") to electronically surveil controlled substances and other "drugs of concern." State PDMPs utilize proprietary, predictive software platforms that deploy algorithms to determine whether a patient is at risk for drug misuse, drug diversion, doctor shopping, or substance use disorder. PDMPs have never been validated by a federal agency or peer review, yet states have mandated their use throughout the health care delivery system.

Research demonstrates that clinical overreliance on the risk scores generated by PDMP algorithms motivates clinicians to refuse to treat—or to inappropriately treat—marginalized and stigmatized patient populations, including individuals with actual or perceived substance use disorder, chronic pain conditions, or other disabilities. The misuse of information generated by PDMP algorithms by healthcare providers is anticipated to impact over one billion patient encounters each year. This Article provides a framework for challenging such PDMP algorithmic discrimination as disability discrimination. It contends that Section 504 of the Rehabilitation Act, the Americans with Disabilities Act, and Section 1557 of the Affordable Care Act can be engaged to protect vulnerable patients from PDMP-related algorithmic discrimination. It then provides recommendations to develop and strengthen the 2024 Section 1557 final rule concerned with clinical-decision algorithmic discrimination, harmonize new

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and existing antidiscrimination protections, and improve implementation and enforcement efforts in this context.

INTRODUCTION

The United States is embroiled in a multi-decade, unprecedented drug overdose crisis. Drug poisoning deaths in America increased by more than 250 percent between 1999 and 2019,[1] reaching a record toll of 107,941 fatalities in 2022.[2] Millions of Americans with substance use disorder ("SUD") need access to evidence-based health care. According to the Substance Abuse and Mental Health Services Administration ("SAMHSA"), 46.3 million teenagers and

1. HEALTH CANADA, PUB. HEALTH AGENCY OF CANADA & U.S. DEP'T OF HEALTH & HUMAN SERVS., CANADA-U.S. JOINT WHITE PAPER: SUBSTANCE USE AND HARMS DURING COVID-19 AND APPROACHES TO FEDERAL SURVEILLANCE AND RESPONSE 1, 2 (2022).

2. *Drug Overdose Deaths: Facts and Figures*, NAT'L INST. ON DRUG ABUSE (Aug. 2024) [hereinafter *Drug Overdose Deaths*], https://nida.nih.gov/research-topics/trends-statistics/overdose-death-rates#Fig1 [https://perma.cc/CG7T-F3A9].

adults experienced SUD in 2021.[3] Of those, 24 million had a drug use disorder, and 9.2 million misused opioids (prescription pain medication or illicit drugs such as heroin) in the past year.[4]

We are concomitantly witnessing a dramatic expansion in the use of algorithmic tools to support clinical decision-making, clinical standards of care, and institutional practices and policies related to patient care—a development often framed as both promising and perilous.[5] Clinical algorithms are tools designed to improve and standardize health care decision-making.[6] They range from flowcharts and clinical guidelines to complex computer algorithms, decision support interventions, and models.[7] Clinical care providers and institutions use these tools for a variety of purposes including screening, risk prediction, diagnosis, prognosis, clinical decision-making, treatment planning, health care operations, and allocation of resources.[8] While expanding the use of these tools holds great promise for improved health care delivery and outcomes, it also can contribute to bias and discrimination as well as exacerbate inequities that impact already disadvantaged groups, including people with SUD, chronic pain conditions, and other disabilities.[9]

This Article identifies an emerging crisis at the intersection of the ongoing drug overdose crisis and the ever-increasing use of clinical algorithms: the misuse of information—which is often incomplete and inaccurate—generated

3. SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., KEY SUBSTANCE USE AND MENTAL HEALTH INDICATORS IN THE UNITED STATES: RESULTS FROM THE 2021 NATIONAL SURVEY ON DRUG USE AND HEALTH 1 (2022).

4. *Id.*

5. NAT'L ACAD. OF MED., ARTIFICIAL INTELLIGENCE IN HEALTH CARE: THE HOPE, THE HYPE, THE PROMISE, THE PERIL 1, 1 (Michael Matheny, Sonoo Thadaney Israni, Mahnoor Ahmed & Danielle Whicher eds., 2019).

6. *Id.* at 1 ("The emergence of artificial intelligence (AI) as a tool for better health care offers unprecedented opportunities to improve patient and clinical team outcomes, reduce costs, and impact population health.").

7. Nondiscrimination in Health Programs and Activities, 87 Fed. Reg. 47824, 47880–84 (proposed Aug. 4, 2022) (to be codified at 45 C.F.R. pt. 92.210) (Use of Clinical Algorithms in Decision-Making, § 92.210).

8. *Id.* at 47880.

9. *See, e.g.*, Ryan Levi & Dan Gorenstein, *AI in Medicine Needs To Be Carefully Deployed To Counter Bias—And Not Entrench It*, NPR (June 6, 2023, 5:00 AM), https://www.npr.org/sections/health-shots/2023/06/06/1180314219/artificial-intelligence-racial-bias-health-care [https://perma.cc/UP4M-DNML] (explaining that "[t]he data these algorithms are built on . . . often reflect inequities and bias that have long plagued U.S. health care"); *Racial Bias in Health Care Artificial Intelligence*, NAT'L INST. FOR HEALTH CARE MGMT. (Sept. 30, 2021), https://nihcm.org/publications/artificial-intelligences-racial-bias-in-health-care [https://perma.cc/9HP3-F64S] (pointing out that "algorithmic predictions accounted for 4.7x more of the racial disparities in pain relative to standard measures"); Trishan Panch, Heather Mattie & Rifat Atun, *Artificial Intelligence and Algorithmic Bias: Implications for Health Systems*, 2 J. GLOB. HEALTH 1, 1 (2019) (defining "algorithmic bias in the context of AI and health systems as: 'the instances when the application of an algorithm compounds existing inequities in socioeconomic status, race, ethnic background, religion, gender, disability or sexual orientation to amplify them and adversely impact inequities in health systems'").

by prescription drug monitoring program ("PDMP") algorithms to guide health care decisions anticipated to impact over one billion patient encounters each year.[10] PDMPs purport to identify and target individuals who have, or who are at risk of, developing SUD,[11] but PDMPs were designed as law enforcement tools and not for clinical application.[12] Uncritical reliance on information from PDMP algorithms and their associated patient risk scores in the clinical setting, moreover, drives refusals to prescribe and treat vulnerable people based on actual, perceived, or past SUD or other disability.[13] Overreliance on PDMP algorithmic information can also motivate institutional policies and practices that exclude or otherwise harm vulnerable patient populations surveilled by PDMPs.[14]

This Article provides a framework for challenging clinical PDMP algorithmic discrimination as disability discrimination. For over fifty years, federal antidiscrimination laws have been used to address discrimination against people with disabilities, including in health care.[15] Section 504 of the Rehabilitation Act,[16] the Americans with Disabilities Act ("ADA"),[17] and Section 1557 of the Patient Protection and Affordable Care Act ("ACA")[18] address forms of disability discrimination in health care that contribute to persistent health inequities experienced by people with disabilities.[19] These laws

10. Michele J. Buonora, Sydney A. Axson, Shawn M. Cohen & William C. Becker, *Paths Forward for Clinicians Amidst the Rise of Unregulated Clinical Decision Support Software: Our Perspective on NarxCare*, 39 J. GEN. INTERNAL MED. 858, 858 (2023).

11. *See, e.g.*, *Prescription Drug Monitoring Programs*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION (May 6, 2024), https://www.cdc.gov/overdose-prevention/hcp/clinical-guidance/prescription-drug-monitoring-programs.html?CDC_AAref_Val=https://www.cdc.gov/opioids/healthcare-professionals/pdmps.html [https://perma.cc/6USJ-MZJZ] ("Information from PDMPs can help clinicians identify patients who may be at risk for overdose [and/or SUD].").

12. *See, e.g.*, Mina Hong, Sarah Seymour, Thomas J. Stopka, Lane Bandanza, Erin Crocker, Allison Morgan & Leo Beletsky, *"Nobody Knows How You're Supposed to Interpret It:" End-User Perspectives on Prescription Drug Monitoring Program in Massachusetts*, 16 J. ADDICTION MED. e171, e171 (2022).

13. Jennifer D. Oliva, *Dosing Discrimination: Regulating PDMP Risk Scores*, 110 CALIF. L. REV. 47, 79–80 (2022) [hereinafter Oliva, *Dosing Discrimination*].

14. *Id.* at 89–102.

15. Lisa I. Iezzoni, Michael M. McKee, Michelle A. Meade, Megan A. Morris & Elizabeth Pendo, *Have Almost Fifty Years of Disability Civil Rights Laws Achieved Equitable Health Care?*, 41 HEALTH AFFS. 1371, 1371 (2022).

16. Rehabilitation Act of 1973, Pub. L. No. 93-112, § 504, 87 Stat. 355, 394 (codified as amended at 29 U.S.C. § 794) (labeling the specific provision prohibiting discrimination in the Rehabilitation Act as § 504).

17. Americans with Disabilities Act of 1990, Pub. L. No. 101-336, 104 Stat. 327 (codified at 42 U.S.C. §§ 12101–213).

18. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1557, 124 Stat. 119, 260 (2010) (codified at 42 U.S.C. § 18116).

19. *See* Nondiscrimination in Health Programs and Activities, 87 Fed. Reg. 47824, 47836–37 (proposed Aug. 4, 2022) (to be codified at 42 C.F.R. pts. 438, 440, 457, and 460; 45 C.F.R. pts. 80,

can be engaged to protect vulnerable patients from PDMP-related algorithmic discrimination in health care. In addition, the 2024 final rule implementing ACA Section 1557 specifically addresses the use of clinical algorithms and other patient care decision support tools by health care providers and entities in light of a growing body of research demonstrating the prevalence of clinical algorithms and other tools to discriminate against marginalized patient populations.[20] As this Article explains, the 2024 Section 1557 final rule presents an opportunity to strengthen the protections provided by existing antidiscrimination laws to people with disabilities, including people who are harmed by the use of PDMP algorithm information and risk scores in health care decision making.

This Article proceeds in four parts. Part I traces the rise of electronic PDMPs as a core punitive strategy to enhance the surveillance of prescription opioids and other controlled substances. It also provides a critical analysis of the development and use of PDMP algorithms and risk scoring models as well as the ever-increasing use of PDMP algorithmic information in clinical decision-making.

Part II of this Article provides an overview of the disability antidiscrimination laws that cover health care services and programs, including the recently emphasized protections for people who are targeted by PDMP algorithms and patient risk scores. It also analyzes the application of those antidiscrimination laws to the health care providers and entities that rely on PDMP algorithmic information.

Part III examines theories of disability antidiscrimination that can be engaged to protect vulnerable populations from health-harming, PDMP-driven health care provider behaviors, including refusals to prescribe or treat patients based on actual, perceived, or past SUD status or other disability often without any individualized, evidence-based assessment of those patients' medical needs. It also describes how disability antidiscrimination theories can address patient exclusions based on unsupported safety concerns and denials of reasonable modifications to policies, practices, and procedures related to the use of information derived from PDMP algorithms and SUD treatment to accommodate the needs of individual patients. Notably, most of the growing body of research highlighting the harms of algorithmic discrimination focuses on the disparate impact that facially neutral algorithms can have on people of

84, 86, 91, 92, 147, 155, and 156) (discussion at III.D.4. Health Equity and Discrimination Related to Disability).

20. Nondiscrimination in Health Programs and Activities, 89 Fed. Reg. 37522, 37645 (May 6, 2024) (to be codified at 45 C.F.R. pt. 92.210) (referring to discussion in 2022 Section 1557 proposed rule); *see also* Nondiscrimination in Health Programs and Activities, 87 Fed. Reg. at 47880–82 (Use of Clinical Algorithms in Decision-Making § 92.210).

color, people with disabilities, or other disadvantaged groups.[21] Unlike the software platforms examined by these scholars, however, PDMP algorithms are not facially neutral. Instead, they are intentionally designed to identify individuals who have or who are perceived to have SUD, and are at risk for drug misuse, abuse, and overdose, by generating risk scores that purport to reveal such information. Accordingly, Part III focuses on disparate treatment theories of disability discrimination.

Part IV concludes the Article by enumerating a set of recommendations aimed at developing and strengthening the 2024 Section 1557 final rule concerned with algorithmic discrimination generally, and PDMP algorithmic discrimination as disability discrimination, specifically. This section proposes that the U.S. Department of Health and Human Services ("HHS") require or strongly encourage covered health care providers and entities to (1) ensure that clinical algorithms are technically and clinically valid, (2) develop publicly available standards governing the use of clinical algorithms that reflect and reinforce existing antidiscrimination protections, and (3) engage in ongoing monitoring and oversight of clinical algorithm use to ensure that such use is equitable at individual and systemic levels by, among other things, developing protocols to identify and correct for potential bias. While these recommendations are focused on PDMP algorithmic discrimination, they are also intended to address the risk of discrimination resulting from the interpretation and use of information derived from a range of clinical algorithms in health care decision making. Part IV also advocates for the harmonization of the regulations implementing Section 1557 with the 2020 Coronavirus Aid, Relief, and Economic Security ("CARES") Act,[22] removal of the ADA's explicit exclusion of individuals who are currently engaged in the illegal use of drugs, and clarification or restoration of access to disparate impact private causes of action under Section 1557, the laws it amends, or both, to enhance the revised rule's impact on health care algorithmic discrimination.

21. *See generally* RUHA BENJAMIN, RACE AFTER TECHNOLOGY: ABOLITIONIST TOOLS FOR THE NEW JIM CODE (2019) (examining how facially neutral algorithms may exacerbate racial hierarchies); VIRGINIA EUBANKS, AUTOMATING INEQUALITY: HOW HIGH-TECH TOOLS PROFILE, POLICE, AND PUNISH THE POOR (2017) (investigating the role of algorithms in distributing resources to the poor); SAFIYA UMOJA NOBLE, ALGORITHMS OF OPPRESSION: HOW SEARCH ENGINES REINFORCE RACISM (2018) (discussing negative biases toward women of color presented by algorithms); CATHY O'NEIL, WEAPONS OF MATH DESTRUCTION: HOW BIG DATA INCREASES INEQUALITY AND THREATENS DEMOCRACY (2016) (detailing various societal infrastructure controlled by algorithms and disparate impacts based on class); FRANK PASQUALE, THE BLACK BOX SOCIETY: THE SECRET ALGORITHMS THAT CONTROL MONEY AND INFORMATION (2015) (discussing lack of transparency in algorithmic function); DOROTHY ROBERTS, FATAL INVENTION: HOW SCIENCE, POLITICS, AND BIG BUSINESS RE-CREATE RACE IN THE TWENTY-FIRST CENTURY (2011) (explaining that myths about race based science promote societal inequality).

22. Coronavirus Aid, Relief, and Economic Security Act, Pub. L. No. 116-136, 134 Stat. 360 (2020) (codified at 21 U.S.C. §§ 356j, 360b–1).

I. THE ADVENT OF PDMPS

A. *Drug Crisis Overview*

The United States is in the midst of a catastrophic and ever-evolving drug crisis, which various commentators continue to characterize as an "opioid overdose epidemic."[23] Preventable drug overdose deaths in America have increased by more than 792% since 1999.[24] In 2020, 91,799 individuals succumbed to fatal drug poisonings, which was the highest annual overdose mortality rate ever recorded in United States history at the time.[25] Unfortunately, that record was shattered in 2021, during which 106,699 people died from drug poisonings across the nation.[26] In August 2024, the Centers for Disease Control and Prevention reported that the United States suffered 107,941 overdose deaths during calendar year 2022.[27]

Death from drug poisoning is an ever-present threat for the millions of Americans who experience SUD. According to SAMHSA, 46.3 million teenagers and adults experienced SUD in 2021.[28] Of those, 24 million had a drug use disorder, and 9.2 million misused opioids (prescription pain medication or illicit drugs such as heroin) in the past year.[29] That stated, only a small number of patients who received long-term opioid therapy in the clinical setting to treat a chronic condition developed opioid use disorder ("OUD").[30]

It is important in the clinical setting to distinguish between patients who are dependent on prescription opioids due to long-term, medically-supervised

23. Evan Wood, Eri D. Solomon & Scott E. Hadland, *University Precautions for People at Risk of Opioid Overdose in North America*, 183 JAMA INTERNAL MED. 401, 401 (2023) (stating that "North America is experiencing an unprecedented opioid overdose epidemic"); Mark Tyndall & Zoe Dodd, *How Structural Violence, Prohibition, and Stigma Have Paralyzed North American Responses to Opioid Overdose*, 22 AMA J. ETHICS 723, 723 (2020) (explaining that, "[a]s of 2020, North America is now into the fifth year of an unprecedented increase in drug overdose deaths driven by a toxic, unpredictable, and unregulated drug supply"); Jordan Trecki, *A Perspective Regarding the Current State of the Opioid Epidemic*, 2 JAMA NETWORK OPEN 1, 1 (2019) (contending that "[t]he United States is currently in the midst of an unprecedented public health crisis related to opioid misuse and dependence").

24. *Drug Overdoses*, NAT'L SAFETY COUNCIL (2024), https://injuryfacts.nsc.org/home-and-community/safety-topics/drugoverdoses/data-details/ [https://perma.cc/MEP6-RT92 (staff-uploaded archive)].

25. *Drug Overdose Deaths*, *supra* note 2.

26. NAT'L INST. ON DRUG ABUSE, NATIONAL DRUG OVERDOSE (OD) DEATHS, 1999-2022, https://nida.nih.gov/sites/default/files/overdose_data_1999-2022_5.2.2024.xlsx [https://perma.cc/ZPW5-VHET (staff-uploaded archive)].

27. *Drug Overdose Deaths*, *supra* note 2.

28. SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., *supra* note 3, at 1.

29. *Id.*

30. Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies*, 374 NEW ENG. J. MED. 1253, 1256 (2016) (explaining that "addiction is not a predictable result of opioid prescribing" and "[a]ddiction occurs in only a small percentage of persons who are exposed to opioids—even among those with preexisting vulnerabilities").

use of those drugs to treat a chronic illness and individuals who suffer from a diagnosable addictive disorder, such as OUD.[31] As explained by Dr. Nora Volkow, who directs the National Institute on Drug Abuse, and her colleagues nearly twenty years ago:

> The term "dependence" has traditionally been used to describe "physical dependence," which refers to the adaptations that result in withdrawal symptoms when drugs, such as alcohol and heroin, are discontinued. Physical dependence is also observed with certain psychoactive medications, such as antidepressants and beta-blockers. However, the adaptations associated with drug withdrawal are distinct from the adaptations that result in addiction, which refers to the loss of control over the intense urges to take the drug even at the expense of adverse consequences.[32]

Consequently, whereas virtually all patients on long-term opioid treatment will develop opioid dependence, only a small subset of that population will develop OUD.[33] The failure to appropriately distinguish between drug dependence, which is a normal physiological response, and SUD in the clinical context is unfortunately common and can cause catastrophic consequences for patients. This is because "misdiagnoses of addictive disorders can lead to a cascade of negative outcomes, including stigma, discontinuation of needed medications, undue scrutiny of both patients and physicians, . . . criminal consequences[, and] . . . treatment that is inappropriate or harmful to a patient."[34]

Conventional wisdom frequently characterizes our shapeshifting drug crisis as either a three or four "overlapping wave phenomenon."[35] According to this narrative, the first wave began in the 1990s and is frequently attributed to a confluence of events, including, among other things, the federal Food and Drug Administration's ("FDA") approval of popular, time-released opioid analgesics, like OxyContin, the aggressive and misleading marketing of those products by their manufacturers, and the medical establishment's re-focused

31. *See generally* Maia Szalavitz, Khary K. Rigg & Sarah E. Wakeman, *Drug Dependence is Not Addiction—And It Matters*, 53 ANNALS MED. 1989 (2021) (explaining "the difference between addiction and physiological dependence" and the dangers of conflating them).

32. Charles P. O'Brien, Nora Volkow & T-K Li, *What's in a Word? Addiction Versus Dependence in DSM-V*, 163 AM. J. PSYCHIATRY 764, 764 (2006).

33. Szalavitz et al., *supra* note 31, at 1990.

34. *Id.* at 1989.

35. CONG. BUDGET OFF., THE OPIOID CRISIS AND RECENT FEDERAL POLICY RESPONSES 1–2 (2022) (contending that "[t]he opioid crisis has occurred in overlapping waves"); Daniel Ciccarone, *The Rise of Illicit Fentanyls, Stimulants, and the Fourth Wave of the Opioid Overdose Crisis*, 34 CURRENT OPS. PSYCHIATRY 344, 344–45 (2021) [hereinafter, Ciccarone, *Fourth Wave*]; Daniel Ciccarone, *The Triple Wave Epidemic: Supply and Demand Drivers of the US Opioid Overdose Crisis*, 71 INT'L J. DRUG POL'Y 183, 183 (2019).

attention on treating and managing chronic pain.[36] Consequently, concerns about drug overdoses and poisoning deaths during this first wave centered around the overprescribing of prescription opioids by health care providers.[37]

During the second wave, which occurred from approximately 2010 to 2013, the country experienced an increase in illicit heroin poisonings.[38] Illicit, synthetic fentanyl quickly replaced heroin as the primary driver of overdose death during the third wave of the crisis beginning around 2013.[39] As the narrative goes, the fourth and current wave is dominated by illicit polydrug overdose poisonings involving dangerous combinations of opiates, depressants, and stimulants, including methamphetamine and cocaine.[40] According to the data, this fourth, polysubstance wave overlaps with earlier waves of the crisis as such overdoses have been on the rise since at least 2015.[41]

Legal and policy responses to the first wave of the "opioid epidemic" singled out prescription opioid overprescribing as the primary causal vector of escalating drug overdose mortality.[42] The prescription opioid-centric framing encouraged the widespread adoption of various supply-side legal and policy tools, including enhanced prescription drug surveillance and strict regulation and criminalization of prescription opioid use and prescribing.[43] Those

36. Oliva, *Dosing Discrimination*, *supra* note 13, at 64–70 (describing the confluence of factors that experts have identified as contributing to the first wave of the drug poisoning crisis); CONG. BUDGET OFF., *supra* note 35, at 1–3, 8, 13–19 (same).

37. Oliva, *Dosing Discrimination*, *supra* note 13, at 64–70; CONG. BUDGET OFF., *supra* note 35, at 8–16.

38. Oliva, *Dosing Discrimination*, *supra* note 13, at 70; CONG. BUDGET OFF., *supra* note 35, at 8; Nabarun Dasgupta, Leo Beletsky & Daniel Ciccarone, *Opioid Crisis: No Easy Fix to Its Social and Economic Determinants*, 108 AM. J. PUB. HEALTH 182, 182–83 (2018); Steven Rich, Meryl Kornfield, Brittany Renee Mayes & Aaron Williams, *How the Opioid Epidemic Evolved*, WASH. POST (Dec. 23, 2019), https://www.washingtonpost.com/graphics/2019/investigations/opioid-pills-overdose-analysis/ [https://perma.cc/4WN2-VUX5 (staff-uploaded, dark archive)].

39. Oliva, *Dosing Discrimination*, *supra* note 13, at 70; CONG. BUDGET OFF., *supra* note 35, at 8; Dasgupta et al., *supra* note 38, at 183; Rich et al., *supra* note 38.

40. Stephen Simpson, *Fentanyl is Dominating Headlines, But There's a More Comprehensive Drug Problem Happening in Texas*, TEX. TRIB. (June 19, 2023, 5:00 AM), https://www.texastribune.org/2023/06/19/texas-fentanyl-drugs/ [https://perma.cc/4DC5-3GEE]; Ciccarone, *Fourth Wave*, *supra* note 35, at 347.

41. MILLENNIUM HEALTH SIGNALS REP., THE "FOURTH WAVE": THE RISE OF STIMULANTS AND THE EVOLUTION OF POLYSUBSTANCE USE IN AMERICA'S FENTANYL CRISIS 4, 7 (2024).

42. We have placed the term "opioid epidemic" in quotations because it leads readers to attribute the problem to prescription opioids notwithstanding the data that establish that the crisis has long been dominated by illicit and often polysubstance drug poisoning deaths.

43. Jeffrey A. Singer, Jacob Z. Sullum & Michael E. Schatman, *Today's Nonmedical Opioid Users Are Not Yesterday's Patients; Implications of Data Indicating Stable Rates of Nonmedical Use and Pain Reliever Use Disorder*, 12 J. PAIN RSCH. 617, 617 (2019) (explaining that the opioid epidemic "narrative drives policies targeting the prescription of opioids to patients in pain, with the goal of reducing the risk of addiction as well as the diversion of prescription opioids to the underground market" and "[t]hese policies include state prescription drug monitoring programs (PDMPs), abuse-deterrent formulations

interventions have been successful insofar as they pushed opioid prescribing rates down to mid-1990s levels, but they have predictably failed to either stabilize or reduce drug poisoning-related deaths.[44] In fact, interventions calibrated to reduce access to prescription opioids, including the mass implementation of PDMPs, may have even exacerbated drug poisoning-related morbidity and mortality[45] because of their role in enhancing the availability and frequency of use of more potent and compact illicit opioids in combination with other unregulated, underground market drugs that increase overdose risk.[46]

It has been long understood that supply-side tactics, such as the enforcement of prohibitionist drug laws and regulations, increase drug poisoning mortality due to substitution effects.[47] In 1986, Richard Cowan coined the phrase, "The Iron Law of Prohibition," to describe the phenomenon by which state-instigated drug prohibition or restriction, such as prescription opioid crackdowns, facilitate the supply and demand of more potent and

of prescription opioids, prescribing guidelines, and legal restrictions on prescribing for both acute and chronic pain"); Leo Beletsky & Corey S. Davis, *Today's Fentanyl Crisis: Prohibition's Iron Law, Revisited*, 46 INT'L J. DRUG POL'Y 156, 156 (2017) (noting that supply-side interventions "have included crackdowns on unscrupulous providers and facilities, prescription limits and guidelines, bolstering prescription monitoring systems, reformulation of some OAs to make them more difficult to misuse, and nudging (or threatening) prescribers to curtail the quantity and dosage of opioid prescriptions").

44. Beletsky & Davis, *supra* note 43, at 156 (positing that "[t]hese efforts have seen some effectiveness in reducing the volume of opioids prescribed, and some have been associated with reductions in prescription opioid overdose mortality" but contributed to an entirely "foreseeable" escalation in overdose deaths).

45. Tyndall & Dodd, *supra* note 23, at 724 ("At all levels, and by any measure, the response to such a massive and ongoing loss of life has been inadequate, as it has focused on prescribing and its downstream effects."); Mohammad S. Jalali, Michael Botticelli, Rachael C. Hwang, Howard K. Koh & R. Kathryn McHugh, *The Opioid Crisis: A Contextual Socio-Ecological Framework*, 18 HEALTH RSCH. POL'Y & SYS. 1, 1 (2020) (opining that, "[w]hile various interventions have been implemented over time, they have generally been insufficient to slow the growth of non-fatal and fatal overdoses at a national level").

46. Maia Szalavitz, *We're Overlooking a Major Culprit in the Opioid Crisis*, 3 SCI. AM. 27, 29 (2021) [hereinafter Szalavitz, *Major Culprit*] (noting that "[j]ournalists continue to echo the three-wave story that places the blame overwhelmingly on pharma . . . [b]ut the second two phases didn't just happen: they were driven by policy choices").

47. Allison L. Pitt, Keith Humphreys & Margaret L. Brandeau, *Modeling Health Benefits and Harms of Public Policy Responses to the US Opioid Epidemic*, 108 AM. J. PUB. HEALTH 1394, 1398 (2018) (concluding that "[p]olicies that reduce the prescription opioid supply may generate both benefits and harms" and that they "decrease addiction-related deaths from prescription pill use but may increase heroin-related deaths as some people with [opioid use disorder] turn to cheaper, more dangerous heroin").

dangerous alternatives, like heroin and fentanyl.[48] Cowan put it this way: "the more intense the law enforcement, the more potent the drugs will become."[49]

The legal and policy interventions aimed at quickly reducing or eliminating opioid prescribing also motivated prescribers to rapidly taper or refuse to prescribe opioid analgesics to chronic pain patients. Such myopic supply-side tactics enhanced the negative health outcomes that attend to individuals with SUD and wrought entirely foreseeable collateral harms on individuals with chronic disabilities who relied on opioid therapeutics to manage their suffering and improve daily functioning. The most ubiquitous of those supply-side surveillance tools are state PDMPs, the origins of which are discussed in the following section.

B. *The Origins of PDMPs*

In response to the first wave of the "opioid epidemic," the federal government embarked on a campaign to incentivize the states to stand up electronic PDMPs to enhance prescription opioid surveillance.[50] To advance this cause, Congress began funding the Harold Rogers Prescription Drug Monitoring Program ("Harold Rogers PDMP") in an annual appropriations bill in 2002.[51] The Harold Rogers PDMP grant is administered by the federal Department of Justice ("DOJ") Bureau of Justice Assistance ("BJA").[52] Since

48. Richard Cowan, *How the Narcs Created Crack: A War Against Ourselves*, 38 NAT'L REV. 26, 26–31 (1986); *see also* Harry G. Levine & Craig Reinarman, *From Prohibition to Regulation: Lessons From Alcohol Policy for Drug Policy*, 69 MILBANK Q. 461, 466–67 (1991) (pointing out that "drug prohibition tends to drive out weaker and milder forms of drugs, and to increase the availability and use of stronger and more dangerous drugs"); Sarah Beller, *Infographic: The "Iron Law of Prohibition*," FILTER MAG. (Oct. 3, 2018), https://filtermag.org/infographic-the-iron-law-of-prohibition/ [https://perma.cc/MB9B-NWR2].

49. Cowan, *supra* note 48, at 27.

50. PRESCRIPTION DRUG MONITORING PROGRAM TRAINING & TECH. ASSISTANCE CTR., TECHNICAL ASSISTANCE GUIDE: HISTORY OF PRESCRIPTION DRUG MONITORING PROGRAMS 3 (2018) [hereinafter PDMP TRAINING & TECH. ASSISTANCE CTR., HISTORY OF PDMPS] ("In 2003, DOJ began the Harold Rogers Prescription Drug Monitoring Grant Program (HRPDMP). DOJ, through its Bureau of Justice Assistance (BJA), made funding available to states that were interested in establishing, implementing, and enhancing PDMPs. The availability of federal funds through the HRPDMP played an integral role in the proliferation of PDMPs."); *see also* Grant Victor, Bradley Ray, Bandon del Pozo, Kaitlyn Jaffe, Andy King & Philip Huynh, *Buprenorphine and Opioid Analgesics: Dispensation and Discontinuity among Accidental Overdose Fatalities in the Indianapolis Metropolitan Area, 2016–2021*, 150 J. SUBSTANCE ABUSE & ADDICTION TREATMENT 1, 1 (2023) (explaining that "[d]uring wave 1 [of the drug poisoning crisis], policymakers implemented guidelines meant to taper or discontinue prescription opioid analgesics, which resulted in most states implementing [PDMPs]").

51. LISA N. SACCO, JOHNATHAN H. DUFF & AMANDA K. SARATA, CONG. RSCH. SERV., R42593, PRESCRIPTION DRUG MONITORING PROGRAMS 16 (2018) ("The Harold Rogers PDMP began receiving federal funding in FY2002 through the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act, 2002 (P.L. 107-77)."). SAMHSA was authorized to provide PDMP grants to the states by the National All Schedules Prescription Electronic Reporting Act of 2005, but SAMHSA has never funded the program. *Id.* at 17–19.

52. *Id.* at 15.

inception, the Harold Rogers PDMP has provided states with hundreds of millions of dollars to implement electronic prescription surveillance systems.[53]

Although the Harold Rogers PDMP is funded by annual federal appropriations as a discretionary, competitive grant program, Congress has never formally authorized the program by statute.[54] Consequently, the grant's underlying purpose is impossible to divine by resorting to legislative history. In fiscal year 2017, the DOJ incorporated the Harold Rogers PDMP into its Comprehensive Opioid Abuse Grant Program, which was authorized by Congress in Section 201 of the Comprehensive Addiction and Recovery Act ("CARA") of 2016.[55]

Section 201 of CARA provides a general description of what PDMPs do—that is, collect, track, and analyze prescription drug data in centralized state electronic databases.[56] It does not, however, state on its face the purposes or objectives of that data collection, tracking, and analysis.[57] In pertinent part, CARA authorizes the DOJ to provide grants to states, tribes, and local governments for any of ten enumerated purposes, including:

> In the case of a State, developing, implementing, or expanding a prescription drug monitoring program to collect and analyze data related to the prescribing of schedules II, III, and IV controlled substances through a centralized database administered by an authorized State agency, which includes tracking the dispensation of such substances, and providing for interoperability and data sharing with each other such

53. Maia Szalavitz, *The Pain Was Unbearable. So Why Did Her Doctors Turn Her Away?*, WIRED (Aug. 11, 2021, 6:00 AM), https://www.wired.com/story/opioid-drug-addiction-algorithm-chronic-pain/ [https://perma.cc/RD72-C9SU] [hereinafter Szalavitz, *The Pain Was Unbearable*] ("Over the past two decades, the US Department of Justice has poured hundreds of millions of dollars into developing and maintaining state-level prescription drug databases—electronic registries that track scripts for certain controlled substances in real time, giving authorities a set of eyes onto the pharmaceutical market.").

54. SACCO ET AL., *supra* note 51, at 16 (providing that "[w]hile the program itself has never been authorized in statute, funding for the program has been provided to DOJ each year through the annual appropriations process").

55. Comprehensive Addiction and Recovery Act of 2016, Pub. L. 114-198, 130 Stat. 695 (codified at 34 U.S.C. § 10701). The DOJ has since changed the name of the Comprehensive Opioid Abuse Program ("COAP") to the Comprehensive Opioid, Stimulant, and Substance Abuse Program ("COSSUP"). *See Comprehensive Opioid, Stimulant, and Substance Abuse Program (COSSUP)*, BUR. OF JUST. ASSISTANCE (Aug. 9, 2023), https://bja.ojp.gov/program/cossup/about [https://perma.cc/9F3U-WSNN].

56. 34 U.S.C. § 10701(a)(6).

57. *Id.*

> program in each other State, and with any interstate entity that shares information between such programs.[58]

While the statutory provisions that authorize the federal government to fund state PDMPs are unhelpful in discerning those databases' objectives, several federal agencies charged with drug control functions have made public statements concerning the purposes of the Harold Rogers PDMP grant program and the objectives of state PDMPs. According to the BJA, the Harold Rogers PDMP "assist[s] state, local, and tribal efforts to break the cycle of substance abuse and misuse by reducing the demand for, use, and illegal trafficking of controlled substances."[59] In 2015, the BJA further reported that "the law enforcement community is increasingly focusing more effort on the investigation and prosecution of criminal activities surrounding prescription drugs," and "PDMPs are a valuable tool in successfully conducting these prescription drug diversion investigations."[60]

The Office of National Drug Control Policy contends that "[a] PDMP is a tool that can be used to address prescription drug diversion and abuse" and, among other things, "help prescribers . . . identify drug-seeking behaviors or 'doctor shopping.'"[61] The federal Drug Enforcement Administration ("DEA"), which concedes that it intensely harvests state PDMP database information, maintains that it does so for two reasons: (1) to identify and investigate pharmaceutical drug diversion, and (2) to set annual controlled substance production quotas.[62]

It is worth pointing out that PDMPs pre-existed the first wave of the current drug poisoning crisis and the authorization of the Harold Rogers PDMP grant in a small number of jurisdictions.[63] New York State created the

58. *Id.*

59. *FY 2022 Harold Rogers Prescription Drug Monitoring Program*, BUR. OF JUST. ASSISTANCE (Apr. 21, 2022), https://bja.ojp.gov/funding/opportunities/o-bja-2022-171290 [https://perma.cc/N49C-EFAF].

60. BUR. OF JUST. ASSISTANCE, JUSTICE SYSTEM USE OF PRESCRIPTION DRUG MONITORING PROGRAMS: OVERVIEW AND RECOMMENDATIONS FOR ADDRESSING THE NATION'S PRESCRIPTION DRUG AND OPIOID ABUSE EPIDEMIC 8 (2015). The BJA Report includes a bulleted list of fifteen ways in which law enforcement utilize PDMPs, which include, among other things, doctor-shopper investigations, identification of altered prescriptions and fraudulent prescriptions, confirmation that a patient is not violating terms of probation or parole, detection of new addresses or telephone numbers for a suspect for a prescription, investigating unlawful prescribing or dispensing, and identification of possible pill mills. *Id.*

61. OFF. OF NAT'L DRUG CONTROL POL'Y, PRESCRIPTION DRUG MONITORING PROGRAMS 1 (2011).

62. DAVID J. MUDD, DRUG ENFORCEMENT ADMIN., PRIVACY IMPACT ASSESSMENT FOR THE PRESCRIPTION DRUG MONITORING PROGRAM ANALYTICS SYSTEM (PDMPAS) 2 (2022).

63. A. Jay Holmgren, Alyssa Botelho & Allan M. Brandt, *A History of Prescription Drug Monitoring Programs in the United States: Political Appeal and Public Health Efficacy*, 110 AM. J. PUB. HEALTH 1191, 1192 (2020).

first PDMP during the Harrison Narcotics Act era[64] by enacting the Boylan Act in 1914.[65] The state superseded the Boylan Act with a less restrictive controlled substances surveillance law just three years later due to "concerns that supply-side restrictions were fueling the illicit opioid market."[66] In 1939, California implemented the California Triplicate Prescription Program, which is characterized as "the oldest continuously operating PDMP program in the country."[67] Between 1939 and 1988, an additional eight states implemented PDMPs.[68]

Like modern PDMPs, these early state PDMPs were used to assist law enforcement to control the prescription of certain controlled substances through criminal investigations and prosecutions and state medical professional boards to surveil and regulate their licensees. As explained by the Prescription Drug Monitoring Program Training and Technical Assistance Center ("TTAC"), "[t]he earliest PDMPs were established primarily as enforcement and regulatory tools providing data to officials responsible for enforcing drug laws and overseeing the prescribing and dispensing of these drugs by health care professionals."[69] As reflected by the above-quoted purpose statements advanced by federal drug control agencies, modern PDMPs continue that legacy.

64. The Harrison Narcotics Act was enacted in 1914 and marks the statutory attempt by the federal government to monitor and control the prescribing and dispensing of "narcotic" substances, such as opium and cocaine, through a federal registration and taxation scheme. *See, e.g.*, David T. Courtwright, *A Century of Narcotic Policy*, *in* 2 INST. OF MED., TREATING DRUG PROBLEMS 1, 9 (Dean R. Gerstein & Henrick J. Harwood eds., 1992); Rufus G. King, *The Narcotics Bureau and The Harrison Act: Jailing the Healers and the Sick*, 62 YALE L.J. 736, 737 (1953).

65. Holmgren et al., *supra* note 63, at 1192. It is worth noting that Americans widely consumed unregulated, over-the-counter patent medicines and other tinctures that included, among other things, "alcohol, morphine, opium, cocaine, heroin, eucaine, chloroform, cannabis indica, chloral hydrate, [and] acetanilide" until those substances were subject to federal regulation in the early twentieth century. *Balm of America: Patent Medicine Collection History*, SMITHSONIAN, https://www.si.edu/spotlight/balm-of-america-patent-medicine-collection/history [https://perma.cc/82V7-8MFP]; *see also* Erick Trickey, *Inside the Story of America's 19th-Century Opiate Addiction*, SMITHSONIAN MAG. (Jan. 4, 2018), https://www.smithsonianmag.com/history/inside-story-americas-19th-century-opiate-addiction-180967673/ [https://perma.cc/8K39-NABV].

66. Holmgren et al., *supra* note 63, at 1192; PDMP TRAINING & TECH. ASSISTANCE CTR., HISTORY OF PDMPS, *supra* note 50, at 2. As New York discovered and as researchers have pointed out throughout the current crisis, PDMP surveillance can instigate patients to switch from a regulated prescription drug to an unregulated illicit drug, the latter of which is more likely to result in overdose or other health harms. *See, e.g.*, David S. Fink, Julia P. Schleimer, Aaron Sarvet, Kiran K. Grover, Chris Delcher, Alvaro Castillo-Carniglia, June H. Kim, Ariadne E. Rivera-Aguirre, Stephen G. Henry, Silvia S. Martins & Magdalena Cerdá, *Association Between Prescription Drug Programs and Nonfatal and Fatal Drug Overdoses*, 168 ANNALS INTERNAL MED. 783, 785–87 (2018) (pointing to studies that associate the implementation of PDMP surveillance with increased inpatient and emergency room visits as well as heroin-related overdoses).

67. PDMP TRAINING & TECH. ASSISTANCE CTR., HISTORY OF PDMPS, *supra* note 50, at 2.

68. *Id.* at 2–3.

69. *Id.* at 1; *see also* Jennifer D. Oliva, *Prescription-Drug Policing: The Right to Health-Information Privacy Pre- and Post-*Carpenter, 69 DUKE L.J. 775, 793 (2020) (explaining that the purpose of PDMPs

Unlike modern PDMPs, however, early PDMPs were markedly homogenous and quite limited in scope and function.[70] These pioneering drug monitoring programs were simple, carbon paper-based systems that limited their surveillance to Schedule II controlled substances—that is, the drugs on the federal Schedule that the DEA has deemed as at greatest risk for misuse.[71] Paper-based PDMPs required prescribers to complete a state-based duplicate or triplicate form at the point of prescribing to provide to patients.[72] The patient then took that form to their pharmacist, who submitted a copy to the designated state PDMP agency after dispensing the drug to the patient.[73]

Only seventeen states operated PDMPs by the end of the twentieth century.[74] Once the federal government began to generously fund those programs through the Harold Rogers PDMP grant in the mid-aughts, however, states implemented electronic PDMPs to surveil prescription drugs at a breakneck pace. Between 2000 and 2010, twenty-seven states adopted and implemented PDMPs—ten more than had come into existence throughout the entire prior century.[75] On October 24, 2018, the federal government enacted the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act,[76] which required all states to have a qualified PDMP no later than October 1, 2021.[77] Today, all fifty states, as well as the District of Columbia, Puerto Rico, Northern Mariana Islands, and Guam, have authorized PDMPs.[78]

C. *Modern PDMPs*

Today's PDMPs differ from their predecessors in myriad material ways. First, modern PDMPs are no longer passive, paper-based databases.[79] They are electronic surveillance software platforms that collect a litany of sensitive

is to "help enforcement agencies identify problem patients, rogue prescribers, and pharmacists who may be diverting potentially addictive and otherwise risky drugs and, thereby, deter aberrant practices in an effort to reduce prescription drug abuse" (internal citations omitted)).

70. PDMP TRAINING & TECH. ASSISTANCE CTR., HISTORY OF PDMPS, *supra* note 50, at 2.

71. *Id.* at 3.

72. *Id.*

73. *Id.*

74. *Id.* at 4.

75. Oliva, *Dosing Discrimination*, *supra* note 13, at 75.

76. Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, Pub. L. No. 115-271, 132 Stat. 3894 (2018) (codified in scattered sections of 5, 15, 18, 19, 21, 26, 29, 34, 38, 40, 42, 49 U.S.C.).

77. *Id.* § 1944, 132 Stat. at 3967–68 (codified at 42 U.S.C. § 1396w-3a).

78. PRESCRIPTION DRUG MONITORING PROGRAM TRAINING & TECH. ASSISTANCE CTR., INTERSTATE PDMP ACCESS AND DATA SHARING ALIGNMENT 18–19 (2021).

79. *See Prescription Drug Monitoring Programs: A Guide for Healthcare Providers*, 10 SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN. 1,1 (2017) ("The first PDMPs, which were paper based, did not provide reports to healthcare providers for use during individual patient care; however, today's electronic databases have a variety of features that make them practical for such care.").

prescribing-related information by requiring drug dispensers to enter a trove of data about every surveilled prescription drug at the point of dispensing.[80] State PDMPs then permit that information to be queried by "authorized users," which vary by jurisdiction but may include prescribers, pharmacists, state medical practice boards, state health departments, correctional supervision, drug treatment providers, drug courts, Medicaid, Medicare, medical examiners, coroners, and federal and state law enforcement.[81] Virtually all states and territories (51) mandate that prescribers access and review a patient's PDMP report under certain circumstances, such as prior to prescribing opioid therapeutics for acute and chronic pain.[82] In addition, federal law requires certain prescribers to check their state PDMP prior to prescribing a controlled substance to a Medicaid beneficiary.[83]

Second, and unlike their predecessors, modern PDMPs are heterogenous across several important characteristics, including the state agency in which they are housed, the specific drugs that they surveil, the specific data that they collect about drugs, patients, prescribers, and dispensers, and, as already mentioned, whom they require to use and permit to access the database.[84] Virtually all states (45) monitor Schedule II–V controlled substances[85] and a majority (38) also surveil an amorphous category of noncontrolled substances characterized as "drugs of concern" (i.e., prescription drugs that are not federal controlled substances but that the state has nonetheless determined are subject to misuse or abuse).[86] One state, Nebraska, monitors every single prescription drug dispensed within its borders.[87]

As noted, state PDMPs vary considerably regarding the type and amount of prescribing-related information that they collect. At a minimum, however, all states demand the following data inputs for every PDMP-monitored drug:

80. PRESCRIPTION DRUG MONITORING PROGRAM TRAINING & TECH. ASSISTANCE CTR., OVERVIEW OF PRESCRIPTION DRUG MONITORING PROGRAMS (PDMPS) 3, 5–7 (2023) [hereinafter PDMP TRAINING & TECH. ASSISTANCE CTR., OVERVIEW OF PDMPS].

81. *See PDMP Policies and Capabilities*, PRESCRIPTION DRUG MONITORING PROGRAM TRAINING & TECH. ASSISTANCE CTR., https://www.pdmpassist.org/Policies/Maps/PDMPPolicies [https://perma.cc/5VPD-2NGY] (scope of authorized users provided under tabs "Solicited Reports: Authorized Users" and "Unsolicited Reports: Authorized Users").

82. *Id.* (reporting that fifty-one states and territories mandate that prescribers use the PDMP).

83. 42 U.S.C. § 1396w-3a.

84. A. Travis Manasco, Christopher Griggs, Rebecca Leeds, Breanne K. Langlois, Alan H. Breaud, Patricia M. Mitchell & Scott G. Weiner, *Characteristics of State Prescription Drug Monitoring Programs: A State-by-State Survey*, 25 PHARMACOEPIDEMIOLOGY & DRUG SAFETY 847, 847 (2016).

85. *See PDMP Policies and Capabilities*, *supra* note 81 (reporting that forty-five states monitor Schedule II-V controlled substances).

86. *See id.* (reporting that thirty-eight states monitor "drugs of concern" in addition to scheduled controlled substances).

87. *Drug Overdose Prevention-PDMP Access*, NEB. DEP'T OF HEALTH & HUMAN SERVS., https://dhhs.ne.gov/Pages/Drug-Overdose-Prevention-PDMP-Access.aspx [https://perma.cc/BN5L-BXNU] (explaining that "all dispensed prescriptions are reported to the PDMP").

the type of drug dispensed, quantity of drug dispensed, number of days a given quantity is supposed to last, date dispensed, prescriber and pharmacy identifiers, and patient identifiers, including name, address, zip code, and date of birth.[88] An additional forty-seven states also collect and monitor the patient's method of payment (e.g., cash, credit, insurance).[89] It has also become increasingly popular for states to integrate into their PDMPs information data from alternative sources, which is often unrelated to prescribing.[90] Such data sources range from medical marijuana dispensations, mental health assessment tools, naloxone administrations, overdose information, criminal court information, and child welfare case information to drug-related convictions.[91]

Third, modern PDMPs are powered by robust data analytics software platforms that deploy algorithms to continuously analyze and assess the myriad prescribing-related data the databases collect concerning prescribers, dispensers, and patients.[92] PDMP software manufacturers identify specific, prescription-related data points collected by the databases as proxies for drug misuse, diversion, and overdose risk.[93] PDMP algorithms then weigh those

88. EDUC. DEV. CTR., USING PRESCRIPTION DRUG MONITORING PROGRAM DATA TO SUPPORT PREVENTION PLANNING, 1, 1–2, 2 n.3, https://pttcnetwork.org/wp-content/uploads/2019/08/pdmp-overview.pdf [https://perma.cc/SU3G-4M57].

89. *See PDMP Policies and Capabilities*, *supra* note 81 (reporting that forty-seven states collect patient method of payment data).

90. *See* PDMP TRAINING & TECH. ASSISTANCE CTR., OVERVIEW OF PDMPS, *supra* note 80, at 5. According to the PDMP Training and Technical Assistance Center,

> many PDMPs received data from alternate sources, such as naloxone administrations or dispensations from first responders, information from medical marijuana dispensaries, drug-related arrest or conviction data, reports of fatal and nonfatal drug overdoses, and reports from pharmaceutical drug manufacturers and distributors on quantities of controlled substance medications sent to dispensers.

Id. There is little public information from PDMP agencies regarding the precise reasons why their databases incorporate specific types of non-prescribing data, but the generic general justification seems to be that such additional information can "better inform health care professionals" in making clinical prescribing determinations. *See, e.g.*, PEW, IMPROVEMENTS TO PRESCRIPTION DRUG MONITORING PROGRAMS CAN INFORM PRESCRIBING 2, 7 (2018).

91. *See PDMP Policies and Capabilities*, *supra* note 81 (enumerating such sources under "Alternative Data Sources" tab).

92. *See NarxCare*, BAMBOO HEALTH, https://web.archive.org/web/20211206023417/https:/bamboohealth.com/solutions/narxcare/ [https://perma.cc/H3P7-TZU3 (staff-uploaded archive)] [hereinafter *NarxCare*, BAMBOO HEALTH] (archived website version) ("NarxCare is an analytics and clinical decision support tool that helps prescribers and dispensers evaluate controlled substance data from Prescription Drug Monitoring Programs (PDMPs) and help prevent substance use disorder and misuse. NarxCare analyzes a patient's PDMP data and provides substance risk scores, an overall overdose risk score, and an interactive visualization of usage patterns."); *Prescription Drug Monitoring Programs*, *supra* note 11 (stating that "PDMP-generated risk scores are created by algorithms in software applied to patient information" and "[s]uch scores have not been validated against clinical outcomes such as overdose and should not take the place of clinical judgment").

93. *See* Oliva, *Dosing Discrimination*, *supra* note 13, at 82.

proxies to generate various numerical drug misuse-related risk scores for each patient in the database.[94]

PDMPs also deploy algorithms to evaluate and score prescriber-specific data to identify "problematic opioid [or other prescription drug] prescribing."[95] Several states have implemented PDMP software that automatically generates and periodically sends to prescribers evaluative "report cards" that, among other things, compare a provider's prescribing behavior to that of their peers.[96] In addition, several states have implemented PDMP platforms that automatically send similar reports concerning "high-risk" or purportedly problematic providers to law enforcement and state regulatory boards.[97] Such practice can trigger a cascade of career-harming events for flagged providers, ranging from criminal investigation and prosecution to licensure suspension and revocation.[98]

94. *Id.* at 82–83.

95. *See, e.g.*, Corey J. Hayes, Johnathan Goree, Jamie Turpin, Haley Ortiz, G. Richard Smith, Srinivasa B. Gokarakonda, Carrie Hyde & Michael A. Cucciare, *Leveraging the Prescription Drug Monitoring Program to Curb Opioid Prescribing in Arkansas*, 43 J. PREVENTION 337, 346 (2022).

96. *See PDMP Policies and Capabilities*, *supra* note 81 (reporting that thirty-eight states have implemented PDMP software that generate provider "report cards"); *see also, e.g.*, Musheng L. Alishahi, Katie Olson, Ashley Brooks-Russell, Jason Hoppe & Carol Runyan, *Provider Reactions to Opioid-Prescribing Report Cards*, 28 J. PUB. HEALTH MGMT. & PRACT. E518, E519 (2022) (explaining that "Appriss Health [now Bamboo Health] the PDMP vendor for Colorado, created the report cards and sent them to prescribers in February 2018" and "[p]rescribers received information comparing their opioid prescribing over the past 6 months with that of other prescribers of the same specialty"); ALASKA PRESCRIPTION DRUG MONITORING PROGRAM, SUMMARY PREPARED FOR THE BOARD OF NURSING Q1 2022 4 (2022), https://www.commerce.alaska.gov/web/Portals/5/pub/PDMP_NURreport_2022_Q1.pdf [https://perma.cc/VBH8-2ZNJ (staff-uploaded archive)] (demonstrating that the Alaska PDMP sends prescribers report cards); JOHN C. GERAGOSIAN & ROBERT J. KANE, STATE OF CONNECTICUT PERFORMANCE AUDIT: CONNECTICUT PRESCRIPTION MONITORING PROGRAM 4, 12–13 (2020). A state audit of Connecticut's PDMP found that

> certain [Connecticut Prescription Drug Monitoring and Reporting Program] features, like automatic alerts about a patient's potential dangerous drug patterns and prescriber report cards, have helped practitioners change their prescribing decisions" and reporting that "the Department of Consumer Protection introduced a prescriber report card utilizing the 2018 Connecticut Prescription Monitoring and Reporting System data. Each quarter, DCP sends these one-page report cards, which provide a snapshot of practitioners' prescribing practices. For example, the report cards show a practitioner's prescribing history compared to their peers within their medical specialty, the top medications prescribed, prescription volumes, and number of patients that exceed certain prescribing thresholds.

Id.

97. Jennifer D. Oliva, *Expecting Medication Surveillance*, 93 FORDHAM L. REV. 509, 516 (2024); PDMP CTR. FOR EXCELLENCE AT BRANDEIS UNIV., GUIDANCE OF PDMP BEST PRACTICES 3 (2014).

98. *See, e.g.*, M. Mofizul Islam & Ian S. McRae, *An Inevitable Wave of Prescription Drug Monitoring Programs in the Context of Prescription Opioids: Pros, Cons and Tensions*, 15 BMC PHARMACOLOGY & TOXICOLOGY 1, 2–7 (2014).

D. *PDMP Migration from Law Enforcement to Health Care*

Despite the initial development of PDMPs by law enforcement for criminal surveillance purposes, PDMP manufacturers and agencies have campaigned to recast these platforms as clinical patient healthcare tools. Bamboo Health (formerly Appriss Health) self-identifies as the leading PDMP software manufacturer in the United States.[99] The company boasts on its website that it supplies PDMP platforms to forty-four states and territories.[100] Bamboo Health "started out in the 1990s making software that automatically notifies crime victims and other 'concerned citizens' when a specific incarcerated person is about to be released."[101] It then transitioned to prescription drug surveillance and health care.

In 2014, Bamboo Health acquired from the National Association of Boards of Pharmacy the first software-generated drug use "risk scoring" platform, NARxCHECK, which provided the company with the opportunity to dominate the state PDMP market.[102] In its press release announcing that deal, Bamboo Health explained that NARxCHECK "supports practitioners by accessing patient prescription information from [PDMPs] . . . , analyzing the data, and providing a risk-based score to assist practitioners in health care decision-making" and that "NARxCHECK can quickly identify those patients who may be at heightened risk for misuse of controlled substances."[103] The company rebranded the risk-scoring software as "NarxCare" and refers to the risk scores that the platform generates as "NarxCare Scores."[104]

99. *Appriss Health & State Governments*, APPRISS HEALTH, https://apprisshealth.com/who-wehelp/state-governments/ [https://perma.cc/VVV2-73LP] (self-identifying Appriss as "[t]he national leader in PDMP solutions" and contending that "[o]ur platform connects most U.S. PDMPs, close to 1 million prescribers and half a million care team members, more than 30,000 pharmacies, and thousands of hospitals, managing more than 400 million monthly transactions").

100. *PMP AWARxE*, BAMBOO HEALTH, https://bamboohealth.com/solutions/pmp-awarxe/ [https://perma.cc/83UT-ZBPT]. Bamboo Health was likely able to monopolize the PDMP software platform market because the company acquired the prevalent prescription opioid risk scoring software at the height of the federal movement to motivate states to implement PDMP surveillance. Oliva, *Dosing Discrimination*, *supra* note 13, at 82.

101. Szalavitz, *The Pain Was Unbearable*, *supra* note 53.

102. Press Release, Appriss Health, Appriss Acquires NARxCHECK from the National Association Boards of Pharmacy Foundation (Nov. 11, 2014), https://apprisshealth.com/pressrelease/appriss-acquires-narxcheck-from-the-national-association-boards-of-pharmacy-foundation/ [https://perma.cc/C5VG-2MXC].

103. *Id.*

104. BAMBOO HEALTH, UP FRONT, EVERY PATIENT, EVERY TIME: A MODEL FOR MAXIMIZING PDMP EFFECTIVENESS 7 (2019), https://bamboohealth.com/wp-content/uploads/2022/10/Whitepaper_Maximizing-PDMP-Effectiveness-PDMP.pdf [https://perma.cc/7ZAZ-5E7W (staff-uploaded archive)].

NarxCare generates four different patient risk scores from PDMP data: a narcotics (opioids) score,[105] a sedative score,[106] a stimulant score,[107] and a composite Overdose Risk Score.[108] Each score is represented by a three-digit number that ranges from 000-999, which purportedly assesses the patient's risk for drug misuse, abuse, overdose, and death.[109]

It is impossible to glean exactly how NarxCare selects, weighs, and values various PDMP data points to generate patient risk scores because Bamboo Health maintains that its algorithms are proprietary and, therefore, not subject to public disclosure.[110] Bamboo Health, however, has revealed in various public-

105. Prescription opioids such as hydrocodone (Vicodin), oxycodone (OxyContin, Percocet), hydromorphone (Dilaudid), oxymorphone (Opana), morphine, codeine, and fentanyl are used to treat moderate to severe pain. *Prescription Opioids DrugFacts*, NAT'L INST. ON DRUG ABUSE (2021), https://nida.nih.gov/publications/drugfacts/prescription-opioids [https://perma.cc/8LUY-L8BX]. Medications indicated to treat opioid use disorder (OUD), such as methadone (Dolophine) and buprenorphine (Suboxone), are also opioids. *Medications to Treat Opioid Use Disorder Research Report*, NAT'L INST. ON DRUG ABUSE (2021), https://nida.nih.gov/publications/research-reports/medications-to-treat-opioid-addiction/overview [https://perma.cc/69RM-EWYD].

106. Central nervous system depressants include sedatives, tranquilizers, and hypnotics, and are used to treat anxiety, panic, acute stress reactions, and sleep disorders. *Misuse of Prescription Drugs Research Report*, NAT'L INST. ON DRUG ABUSE (2018), https://nida.nih.gov/publications/drugfacts/prescription-cns-depressants [https://perma.cc/XM3V-44A7]. Classes of drugs in this category include: benzodiazepines such as diazepam (Valium), clonazepam (Klonopin), alprazolam (Xanax); hypnotics such as zolpidem (Ambien); and barbiturates such as phenobarbital (Luminal). *Id.*

107. Stimulant medications such as dextroamphetamine (Dexedrine), dextroamphetamine/amphetamine combination products (Adderall), and methylphenidate (Ritalin) are generally used to treat attention deficit hyperactivity disorder ("ADHD") and narcolepsy (uncontrollable episodes of deep sleep). *Id.*

108. BAMBOO HEALTH, *supra* note 104, at 7.

109. APPRISS HEALTH, ABOUT NARXCARE: FOR PATIENTS AND THEIR FAMILIES 2 (2019), https://www.floridahealth.gov/statistics-and-data/e-forcse/narxcare-patient-information-sheet.pdf [https://perma.cc/JAN7-Y9ZM] [hereinafter APPRISS HEALTH, ABOUT NARXCARE] (explaining that the risk factors that NarxCare uses to generate patient risk scores "are critical to identifying the risk of a patient for misuse, abuse, overdose, and death"); BAMBOO HEALTH, *supra* note 104, at 7; J.E. HUIZENGA, B.C. BRENEMAN, V.R. PATEL, A. RAZ & D.B. SPEIGHTS, NARXCHECK SCORE AS A PREDICTOR OF UNINTENTIONAL OVERDOSE DEATH 3 (2016), https://apprisshealth.com/wp-content/uploads/sites/2/2017/02/NARxCHECK-Score-as-a-Predictor.pdf [https://perma.cc/K662-G8PS].

110. Oliva, *Dosing Discrimination*, *supra* note 13, at 50, 83; GERAGOSIAN & KANE, *supra* note 96, at 12 (explaining that the "NarxCare report uses specific scores for narcotics, sedatives, and stimulants based on an algorithm factoring in patient risk factors" in order to indicate when "a patient may be at high drug overdose or abuse risk"); HUIZENGA ET AL., *supra* note 109, at 3 ("NARxCHECK is a patented algorithm that analyzes controlled substance data from PDMPs and provides easy-to-use insights into a patient's controlled substance use."). It is commonplace under American law for private company-developed and patented healthcare clinical decision support ("CDS") software platforms, such as NarxCare, to be proprietary and, thus, shielded from disclosure, regulation, and external validation. *See, e.g.*, Michele J. Buonara, Sydney A, Axson, Shawn M. Cohen & William C. Becker, *Paths Forward for Clinicians Amidst the Rise of Unregulated Clinical Decision Support Software: Our Perspective on NarxCare*, 399 J. GEN. INTERNAL MED. 858, 858–59 (2023). The FDA has issued guidance concerning its oversight of such CDS under the agency's Software as a Medical Device

facing materials that it views certain "PDMP elements" as indicative of risk and, therefore, factors those elements into its risk scores. Those elements include: (1) "[t]he number of prescribers a patient has"; (2) "[t]he number of pharmacies at which a patient fills medications"; (3) "[t]he amount or strength of medication being prescribed"; (4) "[t]he amount of additional medications (if any) that may increase the potency (or risk) of other medications" and (5) "[t]he number of times prescriptions overlap with other prescriptions from different prescribers."[111]

The Indiana PDMP User Support Manual, which uses the Appriss Health (now Bamboo Health) logo and commentary identical to that in Bamboo Health's publicly available marketing materials, further states: "The NarxCare platform is designed to accommodate additional, non-PDMP data sources such as claims data, registry data, continuity of care documentation, etc. As these data become available, they will be visually incorporated as additional risk indicators and eventually be included in existing and new algorithms."[112] As previously discussed, states have already begun incorporating a wide variety of alternative data sources into their PDMPs, ranging from criminal justice and child welfare data to mental health and marijuana dispensing information.[113] As one group of researchers explained, the inclusion of these types of alternate data sources in PDMPs is concerning because the information they collect "reflect[s] systemic inequalities in society, yet are unrelated to clinical care."[114] For example, the incorporation of criminal legal system data is likely to disparately impact patients who are racialized as Black while the inclusion of sexual abuse and trauma histories is likely to disparately impact women patients.[115] In addition, a 2021 study specifically found that "patients with higher pain severity or interference, those who were widowed, on leave, retired, or disabled, were most likely to have artificially elevated Narx Scores."[116]

("SaMD") authority but has thus far failed to regulate NarxCare. *Id.* at 859; Oliva, *Dosing Discrimination*, *supra* note 13, at 103.

111. APPRISS HEALTH, ABOUT NARXCARE, *supra* note 109, at 2; *see also* BAMBOO HEALTH, *supra* note 104, at 8.

112. APPRISS HEALTH, IND. PRESCRIPTION MONITORING PROGRAM PMP AWARXE REQUESTOR USER SUPPORT MANUAL app. at 56 (2020) (on file with the North Carolina Law Review) [https://perma.cc/VJX3-TLDB (staff-uploaded archive)]; *see also* FLA. PDMP AWARXE/NARXCARE USER SUPPORT MANUAL 37 (2018), https://www.floridahealth.gov/statistics-and-data/e-forcse/health_care_practitioners/_documents/hc-userguide.pdf [https://perma.cc/2EH8-89Y9].

113. *See PDMP Policies and Capabilities*, *supra* note 81 (enumerating such sources under "Alternative Data Sources" tab).

114. Buonora et al., *Paths Forward*, *supra* note 10, at 860.

115. Oliva, *Dosing Discrimination*, *supra* note 13, at 101–02.

116. Buonora et al., *Paths Forward*, *supra* note 10, at 859–60.

It is important to highlight that NarxCare neither collects nor evaluates patient diagnoses or other health care conditions.[117] PDMPs also do not collect that data. The NarxCare risk scoring algorithms, therefore, must treat a patient with stage four cancer and a patient with a minor ankle sprain as identical and, therefore, view those patients as equally indicated for analgesic treatment. To this point, one study examining patients identified as engaging in "doctor and pharmacy shopping" found that nearly twenty percent of the patients identified were diagnosed with cancer, necessitating visits with multiple prescribers and pharmacies, and therefore falsely flagged as "high risk."[118] Although such outcomes are mind-boggling, especially in the context of clinical decision-making, Bamboo Health owns up to it. In one of its patient-facing marketing pamphlets, Bamboo Health attests that "the [PDMP] data [that is used to generate risk scores] is treated the same for every patient regardless of where they live, their age, sex, race, or *any other attribute*."[119]

Bamboo Health, along with several state PDMP agencies, expressly takes the position that NarxCare and the risk scores that it generates are designed to improve patient health outcomes.[120] The company also explicitly states in its marketing materials, that, while "[m]any PDMPs started as law enforcement tools, . . . most have migrated to a clinical decision support with hopes that providers and pharmacists will more carefully consider and manage the risks and benefits of opioids and other controlled substances."[121] These self-serving claims raise a confounding question: if one of the aims of NarxCare is to improve clinical care in this context, why is it that NarxCare refuses to track patient outcomes? The most plausible answer is that NarxCare does not measure

117. Oliva, *Dosing Discrimination*, *supra* note 13, at 88; Szalavitz, *The Pain Was Unbearable*, *supra* note 53 (reporting that Bamboo "told WIRED that NarxCare and its scores 'do not include any diagnosis information' from patient medical records").

118. Chris Delcher, Daniel R. Harris, Changwe Park, Gail K. Strickler, Jeffery Talbert & Patricia R. Freeman, "*Doctor and Pharmacy Shopping": A Fading Signal for Prescription Opioid Use Monitoring?*, 221 DRUG & ALCOHOL DEPENDENCE 108618, 108620 (2021).

119. APPRISS HEALTH, ABOUT NARXCARE, *supra* note 109, at 2–3 (emphasis added).

120. *NarxCare: Improve Patient Outcomes*, BAMBOO HEALTH, https://bamboohealth.com/solutions/narxcare/ [https://perma.cc/7ZBH-GH63] (current website) (contending that NarxCare "helps providers identify potential risk factors and helps them to make more informed clinical decisions, *with the goal of improving care outcomes*" (emphasis added)).

121. BAMBOO HEALTH, *supra* note 104, at 3. CDS software platforms are widely used by hospital systems and providers in the United States. *See generally*, Zhao Chen, Ning Lang, Haili Zang, Huizhen Li, Yijui Yang, Xingyu Zong, Yaxin Chen, Yanping Wang & Nannan Shi, *Harnessing the Power of Clinical Support Systems: Challenges and Opportunities*, OPEN HEART at 1 (Nov. 28, 2024), https://pmc.ncbi.nlm.nih.gov/articles/PMC10685930/pdf/openhrt-2023-002432.pdf [https://perma.cc/XR9D-JVD7] (explaining the positive impacts associated with the implementation of CDS systems); Reed T. Sutton, David Pincock, Daniel C. Baumgart, Daniel C. Sadowski, Richard N. Fedorak & Karen I. Kroeker, *An Overview of Clinical Decision Support Systems: Benefits, Risks, and Strategies for Success*, NJP DIGITAL MEDICINE at 1 (Feb. 6, 2023), https://pmc.ncbi.nlm.nih.gov/articles/PMC7005290/pdf/41746_2020_Article_221.pdf [https://perma.cc/NT5M-4ZC5] (describing the benefits that CDS systems provide to hospitals).

its success on patient outcomes; instead, it is myopically focused on reducing opioid prescribing entirely divorced from its algorithms' impacts on patient health and safety.

Another theory is that tracking patient health outcomes would undermine Bamboo Health's claims that the clinical use of NarxCare improves patient care. Several studies that evaluated PDMPs associate them with *increased illicit drug overdose mortality* and other negative health outcomes.[122] For example, the implementation of state PDMPs has been associated with significant increases in prescription opioid and heroin-related treatment admissions in several jurisdictions.[123] The United States' ever-escalating drug poisoning morbidity and mortality statistics seem consistent with these conclusions.

It is worth emphasizing that NarxCare PDMP risk scoring algorithms have neither been externally validated by peer review nor the FDA,[124] the latter of which has the authority to vet and regulate predictive clinician decision software, like NarxCare, under its Software as a Medical Device ("SaMD") authority.[125] The validity of NarxCare-like risk scores has, however, been called

122. This is because PDMP implementation and surveillance can motivate patients to switch from a regulated prescription drug on which they are physically dependent to an unregulated illicit drug, the latter of which is more likely to result in overdose or other health harms. *See* Young Hee Nam, Dennis G. Shea, Yunfeng Shi & John R. Moran, *State Prescription Drug Monitoring Programs and Fatal Overdose*, 23 AM. J. MANAGED CARE 297, 300 (2017) (concluding that "[i]n the extended model, PDMPs were associated with significantly increased mortality rates for illicit drugs . . . and cocaine" and "[i]n the subcategory analysis, longer-standing PDMPs were associated with significantly increased mortality rates in several categories, including legal narcotics, illicit drugs, cocaine, other and unspecified drugs . . . and illicit drugs and cocaine"); Guohua Li, Joanne E. Brady, Barbara H. Lang, James Giglio, Hannah Wunsch & Charles DiMaggio, *Prescription Drug Monitoring and Drug Overdose Mortality*, 1 INJ. EPIDEMIOLOGY 1, 3 (2014) (concluding that "implementation of PDMPs was associated with an 11% increase in drug overdose mortality"); *see also* Ellen Meara, Jill R. Horwitz, Wilson Powell, Lynn McClelland, Weiping Zhou, A. James O'Malley & Nancy E. Morden, *State Legal Restrictions and Prescription-Opioid Use Among Disabled Adults*, 375 NEW ENG. J. MED. 44, 48–49 (2016) (finding no association between PDMPs and doctor shopping and diversion).

123. *See* Emily Rhodes, Maria Wilson, Alysia Robinson, Jill A. Hayden & Mark Asbridge, *The Effectiveness of Prescription Drug Monitoring Programs at Reducing Opioid-Related Harms and Consequences: A Systematic Review*, 18 BMC HEALTH SERVS. RSCH. 1, 4 (2019). It is worth noting that PDMPs are notoriously difficult to study with statistical models for several reasons. Among other things, PDMP research is challenging because PDMPs are (1) heterogenous in their structure, data capture methods and scope, and utilization by prescribers and (2) rarely implemented in isolation from other federal and state substance use disorder inventions that can have independent impacts on patient outcomes. *Id.* at 7–9.

124. Duncan C. McElfresh, Lucia Chen, Elizabeth Oliva, Vilija Joyce, Sherri Rose & Suzanne Tamag, *A Call for Better Validation of Opioid Overdose Risk Algorithms*, 30 J. AM. MED. INFORMATICS ASS'N 1741, 1743 (2023) (observing that "NarxCare-ORS has *never been clinically evaluated*").

125. Oliva, *Dosing Discrimination*, *supra* note 13, at 107–15; *see also* Cathleen London, *Predicting Drug Diversion: The Use of Data Analytics in Prescription Drug Monitoring*, STUDENT J. INFO. PRIV. (Nov. 15, 2021), https://sjipl.mainelaw.maine.edu/2021/11/15/predicting-drug-diversion-the-use-of-data-analytics-in-prescription-drug-monitoring/#_ftnref30 [https://perma.cc/9ZEL-HGXY] (noting that NarxCare "leverages a black box algorithm that has never been subject to outside or peer evaluation").

into serious question. Dr. Angela Kilby, a Northeastern University health economist, recently put NarxCare to the test.[126]

Dr. Kilby created a machine learning algorithm modeled after NarxCare and tested it on a commercially available insurance claims database to evaluate the model's "clinical value and fairness."[127] Her findings were startling. Even when she chose a cutoff threshold at the 99th percentile of the score distribution (and, thus, only evaluated the accuracy of the risk scores of the highest one percent of all patient scores), she found that *the algorithm generated false positives eighty-nine percent of the time*.[128] At the 95th percentile cutoff threshold of the score distribution, the accuracy of the algorithm eroded from 11% to 4.5%.[129] As Dr. Kilby explained, "[t]he 95th and 99th percentile thresholds are common in literature for predicting opioid use disorder: guidance to prescribers for the commercial [NarxCare risk scores] specifically calls out the clinical utility of thresholds set at those two levels."[130] In other words, Bamboo Health acknowledged in its prescriber-facing materials that Dr. Kilby used the appropriate score distribution metrics in her validation study to assess the NarxCare risk scoring algorithm.

Dr. Kilby was subsequently interviewed about her study and succinctly explained the obvious: the NarxCare risk scoring "algorithm essentially cannot do what it claims to do, which is determine whether writing or denying someone's next prescription will alter their trajectory in terms of addiction."[131] Specifically, she said "[t]here is just no correlation whatsoever between the likelihood of being said to be high risk by the algorithm and the reduction in the probability of developing opioid use disorder."[132] Dr. Kilby concluded her study findings as follows:

> We find that the machine identifies high risk for opioid use disorder based on a few key demographic characteristics, as well as flagging complex chronic pain patients with a number of comorbidities as high risk, but these patients do not on average benefit from a reduction in prescribing more than any other group. In fact, results suggest that reallocating prescribing according to machine recommendation, in a quantity-neutral manner, away from groups with high risk scores and

126. Angela E. Kilby, Algorithmic Fairness in Predicting Opioid Use Disorder Using Machine Learning 1 (Jan. 2021) (unpublished manuscript presented at FAccT '21: Proceedings of the 2021 ACM Conference on Fairness, Accountability, and Transparency) (on file with the North Carolina Law Review).

127. *Id.* at 4, 6.

128. *Id.* at 10.

129. *Id.* at 10–11.

130. *Id.* at 11.

131. Szalavitz, *The Pain Was Unbearable*, *supra* note 53.

132. *Id.*

towards groups with low risk scores, might paradoxically *increase* the prevalence of opioid use disorder.[133]

In sum, the use of NarxCare risk scoring algorithms in the clinical care setting appears more likely to enhance patient harms than improve patient health outcomes by mischaracterizing patient SUD risk and, thereby, instigating prescribers to refuse to treat or inappropriately treat patients. Such consequences counsel against the migration of surveillance tools created for law enforcement purposes to the clinical setting.

II. DISABILITY LAW FRAMEWORK

Despite the flaws and deficiencies described above, PDMP algorithm-generated information is increasingly being used to guide clinical decision-making and to establish standards of care.[134] The incursion of punitive and surveillance-oriented PDMP information and tools into clinical settings contributes to serious inequities and harms the health and wellbeing of people with SUD and other disabilities, generally, and people with SUD and other disabilities perceived as belonging to other marginalized and stigmatized groups, specifically.[135]

133. Kilby, *supra* note 126, at 4.

134. *See, e.g.*, PEW, *supra* note 90, at 2 (explaining that "PDMP administrators noted that morphine equivalent dosage (MED) calculations—a standardized measure that can help assess dose-related risk of overdose—and other thresholds that indicate risk are valuable data to include in the patient profile" but that "some were concerned that this condensed information might dissuade prescribers from examining patient profiles in detail"). Pew reported that "[r]esearch indicates that once a prescriber accesses PDMP data, there can be significant differences in how the data are interpreted and applied to clinical decision-making." *Id.* 3; *see also* Dan Martin, *Think Like a Prosecutor: How Physicians Can Address the Threat of Data Mining-Based Fraud Investigations*, MED. ECONOMICS (July 25, 2023), https://www.medicaleconomics.com/view/think-like-a-prosecutor-how-physicians-can-address-the-threat-of-data-mining-based-fraud-investigations [https://perma.cc/7UTV-X4P4]. According to Dan Martin,

> the DOJ has used data mining to target physicians whose opioid prescriptions—in terms of total number of patients receiving such prescriptions and the average dosage prescribed—exceed certain benchmarks (benchmarks that evolve over time and often are determined to be flawed, such as the Centers for Disease Control and Prevention's widely publicized 90 morphine milligram equivalent "limit" that it later disavowed).

Id.

135. Oliva, *Dosing Discrimination*, *supra* note 13, at 97 ("NarxCare risk scoring likely exacerbates existing disparities in chronic pain treatment for Black patients, women, individuals who are socioeconomically marginalized, rural individuals, and patients with complex, co-morbid disabilities and OUD."); *see also id.* at 97–102; Leo Beletsky, *Deploying Prescription Drug Monitoring Programs to Address the Overdose Crisis: Ideology Meets Reality*, 15 IND. HEALTH L. REV. 139, 142 (2018) (Prescription drug "[m]onitoring programs and the predictive technologies that they deploy may perpetuate biases and [have a] disproportionate impact on underprivileged citizens, given their common roots with other kinds of surveillance of poor, immigrant, and stigmatized communities.").

Disability law offers a distinctive framework and set of tools to recognize and remedy forms of algorithmic discrimination in health care that harm people with disabilities, including people with SUD. This section provides an overview of the ADA, Section 504 of the Rehabilitation Act of 1973, and Section 1557 of the ACA as applied to health care services, programs, and activities. These laws apply to health care providers and entities that rely on information derived from PDMP algorithms and extend protections to people who are targeted by PDMP algorithms and risk scores.

The Rehabilitation Act prohibits discrimination against people with disabilities in programs and activities that receive federal financial assistance, including health care programs and activities.[136] Congress enacted the ADA in 1990 with the aim of expanding the Rehabilitation Act's protections to address widespread discrimination against people with disabilities and to ensure their integration and equal opportunity in all areas of American life, including public and private health care.[137] Title II of the ADA applies to state and local government programs, services, and activities.[138] Title III applies to places of public accommodations, regardless of federal funding.[139]

Section 1557 of the ACA amended existing antidiscrimination laws to provide additional protections to patients in certain health care programs, activities, and settings.[140] Section 1557 provides that

> an individual shall not, on the ground prohibited under title VI of the Civil Rights Act of 1964, title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975, or section 504 of the Rehabilitation Act of 1973 . . . be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any

136. Rehabilitation Act of 1973, Pub. L. No. 93-112, § 504, 87 Stat. 355, 394 (codified as amended at 29 U.S.C. § 794).

137. Americans with Disabilities Act of 1990, Pub. L. No. 101-336, 104 Stat. 327 (codified as amended at 42 U.S.C. §§ 12101–12213); *see* U.S. DEP'T OF JUST. C.R. DIV., A GUIDE TO DISABILITY RIGHTS LAWS (2020), https://www.ada.gov/cguide.htm [https://perma.cc/GZW3-MQAQ].

138. 28 C.F.R. § 35.102 (2020) (providing that Title II applies to "services, programs, and activities provided or made available by public entities").

139. U.S. DEP'T OF JUST. C.R. DIV., ADA TITLE III TECHNICAL ASSISTANCE MANUAL (2020), https://www.ada.gov/resources/title-iii-manual/ [https://perma.cc/YM48-6G5R] [hereinafter U.S. DEP'T OF JUST. C.R. DIV., TITLE III MANUAL]; *see also* 42 U.S.C. § 12181(7)(F).

140. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1557(a), 124 Stat. 119, 260 (2010) (codified as amended at 42 U.S.C. § 18116(a)).

> program or activity that is administered by an Executive Agency or any entity established under this title (or amendments).[141]

The U.S. Department of Health and Human Services ("HHS") Office for Civil Rights ("OCR") is responsible for enforcing Title II of the ADA, Section 504 of the Rehabilitation Act, and Section 1557 of the ACA.[142] The DOJ is also charged with enforcing Section 504, Title II and III of the ADA, and Section 1557 of the ACA.[143] Because Section 1557 incorporates the Rehabilitation Act, judicial and regulatory interpretation of the Rehabilitation Act's requirements and enforcement mechanisms are essential to understanding the scope of nondiscrimination protections under Section 1557.[144] Many provisions of the ADA are similarly relevant, given HHS's positions that Section 504 and Title II of the ADA generally impose substantially the same requirements,[145] and that the final rule interpreting Section 1557 incorporates many of the ADA's regulatory mandates.[146]

A. *PDMP Algorithms Target Protected Individuals*

As noted above, 46.3 million teenagers and adults experienced SUD in 2021, and, of those, 24 million had a drug use disorder, and 9.2 million misused opioids in the past year.[147] In addition, approximately twenty percent of Americans are impacted by chronic pain conditions for which they may be indicated prescription opioid therapy.[148]

A recent analysis of nationally representative data demonstrates that people with disabilities have higher rates of opioid use, misuse, and OUD

141. *Id.*

142. U.S. DEP'T OF HEALTH & HUMAN SERVS., DISCRIMINATION ON THE BASIS OF DISABILITY (2023), https://www.hhs.gov/civil-rights/for-individuals/disability/index.html [https://perma.cc/8P2N-FKRP]; *see also* discussion of enforcement *infra* Section IV.B.

143. *Disability Rights Section*, U.S. DEP'T OF JUSTICE C.R. DIV., https://www.justice.gov/crt/disability-rights-section [https://perma.cc/ZL49-UEGL].

144. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1557(b), 124 Stat. 119, 260 (2010) (codified as amended at 42 U.S.C. § 18116(b)) ("Nothing in this title . . . shall be construed to invalidate or limit the rights, remedies, procedures, or legal standards available to individuals aggrieved under title VI of the Civil Rights Act of 1964, title IX of the Education Amendments of 1972, [S]ection 504 of the Rehabilitation Act of 1973, or the Age Discrimination Act of 1975, or to supersede State laws that provide additional protections against discrimination on any basis described in subsection (a).").

145. Nondiscrimination in Health Programs and Activities, 87 Fed. Reg. 47824, 47841 (proposed Aug. 4, 2022) (to be codified at 42 C.F.R. pt. 92.210).

146. Nondiscrimination in Health Programs and Activities, 80 Fed. Reg. 27522, 37700 (May 6, 2024) (to be codified at 45 C.F.R. pts. 92.202–.205).

147. SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., *supra* note 3, at 1.

148. James M. Dahlhamer, Eric M. Connor, Jonaki Bose, Jacqueline W. Lucas & Carla E. Zelaya, *Prescription Opioid Use Among Adults with Chronic Pain: United States, 2019*, 162 NAT'L HEALTH STATS. REP. 1, 1 (2021).

relative to people without disabilities.[149] The study found that having a disability "increased the odds of opioid misuse and disorder by 31% to 54%" and that people with vision, cognitive, or multiple impairment disabilities experienced higher rates of opioid misuse and OUD.[150] The study goes on to explain that such results "may reflect a higher frequency of unresolved chronic pain needs for certain disability populations, particularly those with multiple limitations."[151]

PDMPs claim to identify individuals who have, or who are perceived to be at risk of developing SUD and to generate risk scores that purport to identify individuals susceptible to or engaged in drug use, misuse, and overdose. Those targeted by PDMPs, including a disproportionate number of patients with co-existing disabilities, are protected by the ADA, Section 504 of the Rehabilitation Act, and Section 1557 of the ACA.

The ADA covers individuals with disabilities, including individuals with a physical or mental impairment that substantially limits a major life activity, individuals with a history of an impairment, and individuals who are regarded as having an impairment.[152] Section 504 of the Rehabilitation Act and Section 1557 of the ACA have adopted the ADA's definition of disability.[153] Congress amended the ADA in 2008[154] to clarify that the statute's definition of disability should be construed in favor of broad coverage.[155]

Federal agencies charged with enforcing antidiscrimination laws in health care have affirmed that SUD satisfies the statutory definition of disability.[156]

149. *See* Young-Rock Hong, Zhigang Xie, Sandhya Yadav, Rebecca Tanner, Catherine Striley & Nicole M. Marlow, *Opioid Use Behaviors Among People with Disability in the United States: An Analysis of the National Survey on Drug Use and Health*, 17 J. ADDICTION MED. e27, e32 (2023).

150. *Id.* at e32–34.

151. *Id.* at e34.

152. Americans with Disabilities Act of 1990, Pub. L. No. 101-336, § 3(2), 104 Stat. 327, 329–30 (codified as amended at 42 U.S.C. § 12102(1)).

153. Rehabilitation Act of 1973, Pub. L. No. 93-112, § 504, 87 Stat. 355, 394 (codified as amended at 29 U.S.C. § 705(9)(B)) (adopting ADA definition of "disability" at 42 U.S.C. § 12102); 45 C.F.R. § 92.102(c) (2023) (adopting the Section 504 definition of "disability" at 29 U.S.C. § 705(9)(B)).

154. ADA Amendments Act of 2008, Pub. L. No. 110-325, § 3, 122 Stat. 3553, 3554–55 (codified at 42 U.S.C. § 12102(4)(A)).

155. 42 U.S.C. § 12102(4)(A).

156. *See, e.g.*, Andrew Joseph, *To Protect People with Addiction from Discrimination, the Justice Dept. Turns to a Long-Overlooked Tool: The ADA*, STATNEWS (June 22, 2022), https://www.statnews.com/2022/06/22/to-protect-people-with-addiction-from-discrimination-the-justice-dept-turns-to-a-long-overlooked-tool-the-ada/ [https://perma.cc/YVB8-68V5].

Recent educational programs,[157] guidance,[158] and agreements[159] from the OCR affirm that individuals with SUD are protected under Title II of the ADA, the Rehabilitation Act, and Section 1557 when the condition substantially limits a major life activity (e.g., caring for oneself, learning, concentrating, thinking, communicating, working, or the operation of major bodily functions, including neurological and brain functions).

The DOJ has similarly affirmed that these disability antidiscrimination laws extend their coverage to people with SUD through regulation,[160] guidance,[161] and several agreements and settlements with private health care entities covered by Title III of the ADA.[162] For example, a 2018 settlement

157. Press Release, OCR Launches Public Education Campaign About Civil Rights Protections in Response to the National Opioid Crisis, U.S. Dep't of Just. (Oct. 25, 2018), https://www.hhs.gov/about/news/2018/10/25/ocr-launches-public-education-campaign-about-civil-rights-protections-in-response-to-the-national-opioid-crisis.html [https://perma.cc/4A5H-QZYY] [hereinafter Oct. 25, 2018 Press Release].

158. U.S. DEP'T OF HEALTH & HUM. SERVS. OFF. FOR C.R., FACT SHEET, DRUG ADDICTION AND FEDERAL DISABILITY RIGHTS LAW 1–2 (2018), https://www.hhs.gov/sites/default/files/drug-addiction-aand-federal-disability-rights-laws-fact-sheet.pdf [https://perma.cc/NDH6-YXSB] [hereinafter U.S. DEP'T OF HEALTH & HUM. SERVS. OFF. FOR C.R., ADDICTION AND DISABILITY RIGHTS]; U.S. DEP'T OF HEALTH & HUM. SERVS. OFF. FOR C.R., NONDISCRIMINATION AND OPIOID USE DISORDER 1–2 (2018), https://www.hhs.gov/sites/default/files/fact-sheet-nondiscrimination-and-opioid-use.pdf [https://perma.cc/E4UD-JJK4] [hereinafter U.S. DEP'T OF HEALTH & HUM. SERVS. OFF. FOR C.R., NONDISCRIMINATION].

159. Press Release, Genesis HealthCare Inc. Agrees to Resolve Allegations of Americans with Disabilities Act Violations, U.S. Dep't of Just. (Aug. 9, 2021), https://www.justice.gov/usao-ma/pr/genesis-healthcare-inc-agrees-resolve-allegations-americans-disabilities-act-violations [https://perma.cc/6UXY-F7ZW] [hereinafter Aug. 9, 2021 Press Release].

160. 28 C.F.R. §§ 35.108(b)(2), 36.105(b)(2) (2023) (defining physical or mental impairment to include "drug addiction").

161. U.S. DEP'T OF JUST. C.R. DIV., THE AMERICANS WITH DISABILITIES ACT AND THE OPIOID CRISIS: COMBATTING DISCRIMINATION AGAINST PEOPLE IN TREATMENT OR RECOVERY 1–5 (2022) [hereinafter U.S. DEP'T OF JUST. C.R. DIV., COMBATTING DISCRIMINATION].

162. Press Release, U.S. Dep't of Just., U.S. Attorney's Office Warns Skilled Nursing Facilities Not to Refuse Treatment to People with Opioid Use Disorder (Sept. 26, 2022), https://www.justice.gov/usao-ma/pr/us-attorneys-office-warns-skilled-nursing-facilities-not-refuse-treatment-people-opioid [https://perma.cc/4Q2T-KWY5] [hereinafter Sept. 26, 2022 Press Release]; Press Release, U.S. Dep't of Just., Four Skilled Nursing Facility Entities Agree to Resolve Allegations of Americans with Disabilities Act Violations (Sept. 27, 2021), https://www.justice.gov/usao-ma/pr/four-skilled-nursing-facility-entities-agree-resolve-allegations-americans-disabilities [https://perma.cc/CJ6D-PQ8D] [hereinafter Sept. 27, 2021 Press Release]; Press Release, U.S. Dep't of Just., U.S. Attorney's Office Settles Disability Discrimination Case With New England Orthopedic Surgeons (May 20, 2021), https://www.justice.gov/usao-ma/pr/us-attorneys-office-settles-disability-discrimination-case-new-england-orthopedic [https://perma.cc/36PX-BJ5W] [hereinafter May 20, 2021 Press Release]; Press Release, U.S. Att'y's Off. Dist. Mass., U.S. Attorney's Office Settles Disability Discrimination Allegations with Operator of Skilled Nursing Facilities (Dec. 29, 2020), https://www.justice.gov/usao-ma/pr/us-attorney-s-office-settles-disability-discrimination-allegations-operator-skilled-0 [https://perma.cc/36PX-BJ5W] [hereinafter Dec. 29, 2020 Press Release]; Press Release, U.S. Dep't of Just., Massachusetts General Hospital Enters Agreement with U.S. Attorney's Office to Better Ensure Equal Access for Individuals with Disabilities (Aug. 7, 2020),

between the DOJ, the OCR, and a skilled nursing facility alleged to have denied admission to patients because they were prescribed medication for OUD confirms that individuals with OUD are protected under the ADA, Section 504, and Section 1557 so long as they "ha[ve] a physical or mental impairment, including opioid addiction, that substantially limits one or more major life activities, which includes the operation of major bodily functions."[163] The DOJ has also made clear that the determination of whether an impairment substantially limits a major life activity must be made without regard to any effect that ameliorating measures—including medication—may have on the impairment at issue.[164] A 2023 agreement between the DOJ, the OCR, and a skilled nursing facility alleged to have denied admission to patients because they were prescribed medication for OUD contained similar statements.[165]

Disability antidiscrimination laws also protect people who are incorrectly assumed to have SUD, or who have a history of treatment for SUD.[166] The "regarded as" prong of the ADA's definition of disability protects people who are incorrectly assumed to be—but who, in fact, are not—misusing drugs,[167] as well as people who take lawfully prescribed opioids or other medications tracked by PDMPs to treat chronic pain or other medical conditions and, thus, are incorrectly assumed to have SUD. Both are common clinical errors motivated by incorrect biased beliefs about PDMP-tracked drugs and the people who use

https://www.justice.gov/usao-ma/pr/massachusetts-general-hospital-enters-agreement-us-attorney-s-office-better-ensure-equal [https://perma.cc/768P-JHSH] [hereinafter Aug. 7, 2020 Press Release]; Press Release, U.S. Dep't of Just., Justice Department Reaches Settlement with Selma Medical Associates Inc. To Resolve ADA Violations (Jan. 31, 2019), https://www.justice.gov/opa/pr/justice-department-reaches-settlement-selma-medical-associates-inc-resolve-ada-violations [https://perma.cc/RKS3-YR7Z] [hereinafter Jan. 31, 2019 Press Release].

163. Aug. 9, 2021 Press Release, *supra* note 159 (settlement agreement citing 42 U.S.C. § 12102); 29 U.S.C. § 705(9) (2023) (adopting ADA definition of "disability" at 42 U.S.C. § 12102(1)); 45 C.F.R. § 92.102(c) (adopting the Section 504 definition of "disability" at 29 U.S.C. § 705(9)(B), and 28 C.F.R. § 36.105(b)(2) (2023) (defining physical or mental impairment to include "drug addiction.")).

164. 42 U.S.C. § 12102(4)(E)(i); *see also* U.S. DEP'T OF JUST., DJ No. 202-36-306, SETTLEMENT AGREEMENT BETWEEN THE UNITED STATES AND CHARLWELL OPERATING, LLC (2018), https://www.ada.gov/charlwell_sa.html [https://perma.cc/MPF4-BGNN].

165. U.S. DEP'T OF HEALTH & HUM. SERVS. OFF. FOR C.R., DJ No. 202-36-341, VOLUNTARY RESOLUTION AGREEMENT BETWEEN THE UNITED STATES OF AMERICA, THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE FOR CIVIL RIGHTS, AND NORTH END REHABILITATION & HEALTHCARE CENTER (2023), https://www.hhs.gov/civil-rights/for-providers/compliance-enforcement/agreements/north-end/index.html [https://perma.cc/5HT4-V8VM] [hereinafter OCR, NORTH END REHABILITATION & HEALTHCARE CENTER].

166. U.S. DEP'T OF JUST. C.R. DIV., COMBATTING DISCRIMINATION, *supra* note 161, at 5.

167. 42 U.S.C. § 12114(b)(3); *see also* Nielsen v. Moroni Feed Co., 162 F.3d 604, 610 (10th Cir. 1998) ("[T]he ADA protects employees who are erroneously regarded as being current illegal drug users.").

them.[168] Consider, for example, an individual with a chronic pain condition not controlled by other medicines who is safely and effectively treated with prescription buprenorphine under the supervision of a physician. Because buprenorphine is a prescription opioid medication that is also used to treat SUD, the individual may be misidentified by the PDMP algorithm or provider as having SUD.

There is no question that many conditions that cause chronic pain also satisfy the statutory definition of disability. It is further worth noting that, among the twenty percent of Americans impacted by chronic pain conditions for which they may be indicated prescription opioid therapy,[169] rates of prescription OUD are surprisingly low: "Around 70 percent of adults have taken medical opioids—yet only 0.5 percent suffer from what is officially labeled 'opioid use disorder.'"[170] Another study found that "even within the age group at highest risk, which are teenagers and people in their early twenties, only one out of every 314 privately-insured patients who had been prescribed opioids developed problems with them."[171] It is, therefore, likely that PDMP algorithms falsely flag as either actively suffering from—or at risk for—OUD an alarming number of patients who belong to a large patient population (individuals with chronic pain conditions) that collectively experience relatively low rates of OUD.[172]

Unfortunately, disability antidiscrimination protections are compromised by the ADA's explicit exclusion of individuals who are currently engaged in

168. Kelly K. Dineen & Elizabeth Pendo, *Engaging Disability Rights Law to Address the Distinct Harms at the Intersection of Race and Disability for People with Substance Use Disorder*, 50 J.L. MED. & ETHICS 38, 43 (2022) [hereinafter Dineen & Pendo, *Engaging Disability Rights Law*].

169. Dahlhamer et al., *supra* note 148, at 1.

170. Szalavitz, *The Pain Was Unbearable*, *supra* note 53.

171. *Id.*

172. *See, e.g.*, Sally Satel, *The Truth About Painkillers*, NAT'L AFFS. (Spring 2021), https://www.nationalaffairs.com/publications/detail/the-truth-about-painkillers [https://perma.cc/4T4B-S5G5] ("A team led by a scholar at the Research Triangle Institute . . . found that 0.12% to 6.1% of half a million chronic-pain patients abused or developed an addiction to opioids within 18 months of starting treatment. The Cochrane Library, a respected independent collection of databases, found that in a combined sample of 2,600 patients drawn from nine separate studies, only 0.27% developed signs of opioid addiction. Another review, co-authored by the director of the National Institute on Drug Abuse and published in the *New England Journal of Medicine*, found '[r]ates of carefully diagnosed addiction [averaging] less than 8 percent' in chronic-pain patients."); *see also* James Wilton, Younathan Abdia, Mei Chong, Mohammad Ehsanul Karim, Stanley Wong, Aaron MacInnes, Rob Balshaw, Bin Zhao, Tara Gomes, Amanda Yu, Maria Alvarez, Richard C. Dart, Mel Krajden, Jane A. Buxton, Naveed Z. Janjua & Roy Purssell, *Prescription Opioid Treatment for Non-Cancer Pain and Initiation of Injection Drug Use: Large Retrospective Cohort Study*, 375 BMJ 1, 1 (2021) (concluding that the "[c]umulative probability of IDU initiation at five years was highest for participants with chronic opioid use (4.0%), followed by those with episodic use (1.3%) and acute use (0.7%), and those who were opioid naive (0.4%)").

illegal drug use,[173] despite the statute's "safe harbor" exception for people who are participating or have participated in a rehabilitation program and are no longer engaged in illegal drug use.[174] Contrary to common misperceptions, taking lawfully prescribed medications to treat SUD is not engaging in the illegal use of drugs.[175] In fact, the OCR has clarified that taking prescription medications, such as methadone or buprenorphine, to treat SUD neither constitutes illegal drug use nor indicates that the individual is "trading one addiction for another or using the [prescription medications] to get high."[176] Moreover, in the context of health care services, the Rehabilitation Act specifically provides that the current use of illegal drugs is not a basis to deny hospital, outpatient facility, drug rehabilitation, vocational rehabilitation program treatment, and other covered programs and services if the individual is otherwise entitled to such services.[177]

For all these reasons, it is clear that PDMPs purport to identify individuals who have, or who are perceived to be at risk of developing, SUD, and that these individuals are protected by disability antidiscrimination laws. These laws also explicitly address the use of PDMPs in health care, as discussed in the next section.

B. *The Final Rule Specifically Addresses Use of Clinical Algorithms*

On July 25, 2022, HHS announced a proposed rule implementing ACA Section 1557.[178] After extensive public comment, HHS promulgated the final

173. 42 U.S.C. § 12114(a); *see also* 29 U.S.C. § 705(20)(C)(i) (Rehabilitation Act); 42 U.S.C. § 3602(h) (Fair Housing Act).

174. 42 U.S.C. § 12114(b)(1)–(3).

175. *See, e.g.*, *Use of Codeine, Oxycodone, and Other Opioids: Information for Employees*, U.S. EQUAL EMP. OPPORTUNITY COMM'N (Aug. 5, 2020), https://www.eeoc.gov/laws/guidance/use-codeine-oxycodone-and-other-opioids-information-employees [https://perma.cc/GW9W-NK83].

176. Press Release, U.S. Dep't Health & Hum. Servs., OCR Secures Agreement with West Virginia to Protect Persons in Recovery from Opioid Use Disorder from Discrimination on the Basis of Disability (May 13, 2020), https:/www.hhs.gov/about/news/2020/05/13/ocr-secures-agreement-west-virginia-protect-persons-recovery-opioid-use-disorder-discrimination-basis-of-disability.htmlasis-of-disability.html [https://perma.cc/VM9C-Z9YR].

177. U.S. DEP'T OF HEALTH & HUM. SERVS. OFF. FOR C.R., ADDICTION AND DISABILITY RIGHTS, *supra* note 157, at 1–2; U.S. DEP'T OF HEALTH & HUM. SERVS. OFF. FOR C.R., NONDISCRIMINATION, *supra* note 157, at 1–2. Similarly, there is no statutory exclusion in the new CARES Act protections for individuals whose patient records reveal or appear to reveal current or past SUD. *See* Kelly K. Dineen & Elizabeth Pendo, *Substance Use Disorder Discrimination and the CARES Act: Using Disability Law To Inform Part 2 Rulemaking*, 52 ARIZ. STATE L.J. 1143, 1144–45 (2020) [hereinafter Dineen & Pendo, *Substance Use Disorder Discrimination*].

178. Nondiscrimination in Health Programs and Activities, 87 Fed. Reg. 47824, 47920 (proposed Aug. 4, 2022) (to be codified at 42 C.F.R. pts. 438, 440, 457, and 460; 45 C.F.R. pts. 80, 84, 86, 91, 92, 147, 155, and 156).

rule on May 6, 2024.[179] The Section 1557 final rule specifically addresses the use of clinical algorithms.[180] It expressly proscribes a covered entity from discriminating against any individual on the basis of race, color, national origin, sex, age, or disability through the use of clinical algorithms in decision-making.[181] Although, as discussed below, individuals experienced discrimination due to the use of clinical algorithms and patient care decision support tools prior to the publication of the final rule, the 2024 final rule explicitly addresses such discrimination by covered healthcare providers and entities.[182]

The 2022 proposed rule defines clinical algorithms as "tools used to guide health care decision-making" that range from "flowcharts and clinical guidelines to complex computer algorithms, decision support interventions, and models."[183] The 2024 final rule replaces the term "clinical algorithm" in the proposed rule with the broader term "patient care decision support tool," which it defines as ''any automated or non-automated tool, mechanism, method, technology, or combination thereof used by a covered entity to support clinical decisionmaking in its health programs or activities."[184] "Examples of patient care decision support tools include, but are not limited to: flowcharts; formulas; equations; calculators; algorithms; utilization management applications; software as medical devices (SaMDs); software in medical devices (SiMDs); screening, risk assessment, and eligibility tools; and diagnostic and treatment guidance tools."[185]

PDMPs clearly fall within the scope of the final rule's definition of a patient care decision support tool. As described above, modern PDMPs are powered by proprietary algorithms that continuously analyze and evaluate a trove of prescribing-related data to evaluate the prescription drug-related behavior of prescribers, dispensers, and patients.[186] PDMP algorithms identify and weigh specific, prescription-related data points they collect from dispensers and other sources as proxies for drug misuse, doctor shopping, drug diversion,

179. Nondiscrimination in Health Programs and Activities, 89 Fed. Reg. 37522, 37522 (May 6, 2024) (to be codified at 42 C.F.R. pts. 438, 440, 457, and 460; 45 C.F.R. pts. 80, 84, 92, 147, 155, and 156).

180. *Id.* at 37642–51.

181. *Id.*

182. *Id.*

183. Nondiscrimination in Health Programs and Activities, 87 Fed. Reg. at 47880.

184. Nondiscrimination in Health Programs and Activities, 89 Fed. Reg. at 37544, 37642–51.

185. *Id.* at 37644.

186. *See NarxCare*, BAMBOO HEALTH, *supra* note 92 ("NarxCare is an analytics and clinical decision support tool that helps prescribers and dispensers evaluate controlled substance data from [PDMPs] and help prevent substance use disorder and misuse. NarxCare analyzes a patient's PDMP data and provides substance risk scores, an overall overdose risk score, and an interactive visualization of usage patterns."); *Prescription Drug Monitoring Programs*, *supra* note 11 (stating that "PDMP-generated risk scores are created by algorithms in software applied to patient information" and "[s]uch scores have not been validated against clinical outcomes such as overdose and should not take the place of clinical judgment").

and overdose risk, and then the algorithms analyze those proxies to generate multiple drug misuse-related risk scores for each patient they surveil.[187] PDMP software manufacturers maintain that their algorithmic risk scores provide "clinical decision support" to assist health care providers "more carefully consider and manage the risks and benefits of opioids and other controlled substances."[188] As discussed in the previous section, health care providers and hospitals increasingly use information generated by PDMP algorithms to guide health care decision-making and policy.

C. *Covered Health Care Entities Rely on Information from PDMP Algorithms*

Together, the ADA, Section 504 of the Rehabilitation Act, and Section 1557 of the ACA cover virtually all health care providers and institutions. Title II of the ADA applies to state and local government programs, services, and activities, which include health care services provided by public hospitals and clinics and state Medicaid programs.[189] Title III of the ADA applies to places of public accommodations, which include private physician offices and private hospitals, private nursing homes, and private SUD treatment programs open to the public, regardless of federal funding.[190] The Rehabilitation Act applies to programs and activities that receive federal financial assistance, which includes SUD treatment programs, hospitals and health clinics, pharmacies, and nursing facilities.[191] Section 1557 extends the reach of the Rehabilitation Act (as well as the other federal laws that Section 1557 amends) by defining "federal financial assistance" to include grants, loans, credits, subsidies, and insurance contracts.[192] Section 1557 also covers most health care providers because the majority receive federal financial assistance, such as Medicare and Medicaid reimbursement.[193]

As detailed above, state law often requires health care providers to check a patient's PDMP record prior to prescribing opioids or other controlled substances.[194] In addition, federal law requires certain prescribers to check the state PDMP prior to prescribing a controlled substance to a Medicaid

187. Oliva, *Dosing Discrimination*, *supra* note 13, at 82–83.

188. BAMBOO HEALTH, *supra* note 104, at 3.

189. *See, e.g.*, 28 C.F.R. §§ 35.101–.999.

190. U.S. DEP'T OF JUST. C.R. DIV., TITLE III MANUAL, *supra* note 139, at 6; *see also* 42 U.S.C. § 12181(7)(F).

191. 29 U.S.C. § 701(c).

192. Nondiscrimination in Health Programs and Activities, 89 Fed. Reg. 37522, 37542 (May 6, 2024) (to be codified at 45 C.F.R. pt. 92.4).

193. HHS had maintained that payments for physician services under Medicare Part B did not constitute federal financial assistance, but the 2024 final rule includes Medicare Part B as federal financial assistance for purposes of Section 1557 and the underlying civil rights statutes it incorporates. *See id.* at 37664–66.

194. *See PDMP Policies and Capabilities*, *supra* note 81 (reporting that fifty-one states and territories mandate that prescribers use the PDMP).

beneficiary.[195] Notwithstanding these mandates, health care providers and institutions are responsible for the individual and programmatic decisions they make in reliance on information from PDMP algorithms, including patient risk scores, under disability antidiscrimination laws. The 2022 Section 1557 proposed rule emphasizes that health care providers and entities are subject to antidiscrimination requirements in decision-making processes.[196] Specifically, it states that "covered entities are responsible for ensuring that any action they take based on a clinical algorithm does not result in discrimination prohibited by this part, irrespective of whether they played a role in designing the algorithm."[197] The 2024 final rule confirms that covered entities must exercise due diligence when acquiring and using clinical algorithms and other patient care decision support tools,[198] and "must make reasonable efforts to mitigate the risk of discrimination resulting from the tool's use in the covered entity's health programs or activities."[199]

In sum, the framework of disability antidiscrimination law applies to health care services and programs, including the recently emphasized protections for people targeted by PDMP algorithms and patient risk scores. The framework also governs the health care providers and entities that rely on PDMP algorithmic information. The following part analyzes specific theories of discrimination within that framework.

III. APPLICATION OF THEORIES OF DISABILITY DISCRIMINATION TO PDMP ALGORITHMIC HARMS

This part analyzes theories of disability discrimination within the disability antidiscrimination framework that can be engaged to challenge specific PDMP-driven health care provider behavior directed at individuals based on actual, perceived, or past SUD status or other disability. Those behaviors include: (1) the refusal to prescribe and treat based on actual, perceived, or past SUD status or other disability, often without individualized, evidence-based assessment of medical needs; and (2) the failure to provide reasonable modifications to policies, practices, and procedures related to use of PDMP algorithmic information to accommodate the needs of individual patients.

Most of the writing about algorithmic discrimination focuses on disparate impact. That literature is concerned with the negative impacts that facially

195. 42 U.S.C. § 1396w-3a.

196. Nondiscrimination in Health Programs and Activities, 87 Fed. Reg. 47824, 47880–84 (proposed Aug. 4, 2022) (to be codified at 45 C.F.R. pt. 92.210).

197. *Id.* at 47883.

198. Nondiscrimination in Health Programs and Activities, 89 Fed. Reg. 37522, 37647–48 (May 6, 2024) (to be codified at 45 C.F.R. pt. 92.210).

199. *Id.* at 37651.

neutral algorithms can have on people of color, people with disabilities, or other marginalized groups.[200] Researchers have documented the capacity of certain algorithmic tools to disparately impact racialized individuals due to the biases inherent in the tools' data proxies.[201] They also have identified the limitations that pertain to challenging facially neutral algorithms on disparate impact grounds.[202]

Unlike the software platforms examined by these scholars, however, PDMP algorithms are not facially neutral. Instead, they are intentionally designed to identify individuals who have or who are perceived to have SUD, and are at risk for drug misuse, abuse, and overdose, by generating risk scores that purport to reveal such information. Accordingly, this part examines disparate treatment theories of disability discrimination that can be deployed to challenge the use of PDMP algorithms in health care decision-making that negatively impact people with disabilities while leaving a more thorough examination of disparate impact claims in this context to a future article.

A. *Refusal to Prescribe or Treat*

Overreliance on PDMP algorithmic information can motivate a health care provider's refusal to provide a patient necessary and clinically-indicated care. Title II of the ADA and Section 504 of the Rehabilitation Act prohibit individual and categorial refusals to treat due to disability.[203] Those provisions require that health care services be delivered in a way that ensures equal access to people with disabilities, subject to some limitations. Title III of the ADA bans discrimination on the basis of disability in the full and equal enjoyment of goods, services, and facilities in covered health care settings.[204] Specifically, Title III prohibits covered providers and entities from imposing or applying

200. *See, e.g.*, BENJAMIN, *supra* note 21, at 1–48; EUBANKS, *supra* note 21, at 1–13; NOBLE, *supra* note 21, at 1–14; O'NEIL, *supra* note 21, at 1–13; PASQUALE, *supra* note 21, at 1–18; ROBERTS, *supra* note 21, at x.

201. Anya E.R. Prince & Daniel Schwarcz, *Proxy Discrimination in the Age of Artificial Intelligence and Big Data*, 105 IOWA L. REV. 1257, 1259–67 (2020); CRYSTAL GRANT, AM. CIV. LIBERTIES UNION, ACLU WHITE PAPER: AI IN HEALTH CARE MAY WORSEN MEDICAL RACISM 1–2; *see also* Request for Information on the Use of Clinical Algorithms That Have the Potential To Introduce Racial/Ethnic Bias Into Healthcare Delivery, 86 Fed. Reg. 12948, 12948 (Mar. 5, 2021); Ziad Obermeyer, Brian Powers, Christine Vogeli & Sendhil Mullainathan, *Dissecting Racial Bias in an Algorithm Used to Manage the Health of Populations*, 366 SCIENCE 447, 447 (2019).

202. Sharona Hoffman & Andy Podgurski, *Artificial Intelligence and Discrimination in Health Care*, 19 YALE J. HEALTH POL'Y, L. & ETHICS 1, 6 (2020) ("This Article argues that algorithmic discrimination may violate Title VI of the Civil Rights Act and Section 1557 of the Affordable Care Act.").

203. General Prohibitions Against Discrimination, 28 C.F.R. § 35.130(b) (2016); Activities, 28 C.F.R. § 36.202(a) (1992).

204. 42 U.S.C. §§ 12181(7)(F), 12182(a); 28 C.F.R. § 36.201(a) (2016).

treatment eligibility criteria that screen out or tend to screen out people with disabilities, unless such criteria can be shown to be necessary.[205]

Despite these protections, a growing number of settlements negotiated by the DOJ and the OCR with health care facilities indicate that health care systems frequently deny prescriptions and treatment to otherwise qualified patients because they have SUD or are receiving medication for SUD treatment (e.g., buprenorphine, naltrexone, or suboxone, which are tracked by PDMPs). Examples include numerous skilled nursing facilities that intentionally excluded people who were being treated for SUD with medication,[206] primary and specialty care facilities that refused to accept appointments for prospective patients with SUD,[207] an orthopedic surgery center that refused treatment to people with SUD based on concerns about managing post-operative pain,[208] and a transplant center that refused a lung transplant because the patient was being treated for SUD.[209]

Studies also prove that individual providers refuse to treat certain patients due to PDMP algorithmic information. A recent review of the literature on the use of PDMPs in clinical settings pointed to multiple studies that included examples of such patient rejection or abandonment, including the refusal to accept a new patient, the discharge of a patient from the practice, and the failure to prescribe certain medications to new or existing patients.[210] The study also explained that the use of PDMP algorithmic information often resulted in stigmatizing clinical responses, reporting that "some participants described the PDMP as a tool with which to 'purge' their practices of 'deceptive' or 'bad'

205. 42 U.S.C. § 12182(b)(2)(A)(i).

206. Press Release, U.S. Dep't of Health and Hum. Servs., HHS Office for Civil Rights Settles with Massachusetts Skilled Nursing Facility Regarding Disability Discrimination (Nov. 13, 2023), https://www.hhs.gov/about/news/2023/11/13/hhs-office-civil-rights-settles-massachusetts-skilled-nursing-facility-regarding-disability-discrimination.html [https://perma.cc/2UBQ-CJJS]; Sept. 26, 2022 Press Release, *supra* note 161; Sept. 27, 2021 Press Release, *supra* note 162; Press Release, U.S. Dep't of Health and Hum. Servs., Massachusetts Healthcare Provider Resolves Allegations of Discriminatory Practices Regarding Patients Needing Opioid Use Disorder Treatment (Dec. 22, 2021), https://www.hhs.gov/about/news/2021/12/22/ma-healthcare-provider-resolves-allegations-discriminatory-practices-regarding-patients-needing-opioid-use-disorder-treatment.html [https://perma.cc/R8WH-WU3G]; Aug. 9, 2021 Press Release, *supra* note 159; Dec. 29, 2020 Press Release, *supra* note 162; Press Release, U.S. Dep't of Just., U.S. Attorney's Office Settles Disability Discrimination Allegations at Skilled Nursing Facility (May 10, 2018), https://www.justice.gov/usao-ma/pr/us-attorney-s-office-settles-disability-discrimination-allegations-skilled-nursing [https://perma.cc/7YD5-7SEL] [hereinafter May 10, 2018 Press Release].

207. Jan. 31, 2019 Press Release, *supra* note 162.

208. May 20, 2021 Press Release, *supra* note 162.

209. Aug. 7, 2020 Press Release, *supra* note 162.

210. Louisa Picco, Tina Lam, Sarah Haines & Suzanne Nielsen, *How Prescription Drug Monitoring Programs Influence Clinical Decision-Making: A Mixed Methods Systemic Review and Meta-Analysis*, 228 DRUG & ALCOHOL DEPENDENCE 1, 8 (2021).

patients, effectively 'scrubbing out' or 'weed[ing]' out 'problem patients' . . . ."[211]

It is well documented that PDMPs influence clinical treatment decisions by disincentivizing the prescribing of surveilled substances, such as opioids, even when those drugs are indicated.[212] A 2021 systemic review of the impact of PDMP use on health care provider clinical decision-making found that the refusal to prescribe and treat patients was common following PDMP utilization.[213] The study observed that "PDMPs are not intended to be the sole driver of clinical decision-making, however it appears in some instances, that decisions are based primarily on PDMP information."[214] Similarly, the California Society of Addiction Medicine ("CSAM") wrote a letter in 2022 to its state PDMP program, California CURES, raising concerns about NarxCare's "opaque algorithms."[215] In that communication, CSAM pointed out that Bamboo Health "has said that the Overdose Risk Score is a screening tool that may call for deeper physician evaluation. However, it is a commonplace fact that screening tools and 'guidelines' very often end up being utilized as if they were diagnostic instruments or dose ceiling regulations."[216]

As a result, and even when they are treated, patients identified as having SUD and those with other disabilities or conditions that require prescription opioid therapy are at risk of receiving different and lower-quality treatment. Because PDMPs surveil all federally controlled substances and other "drugs of concern" at the option of the state, many people with varying conditions and disabilities are negatively impacted by information generated by PDMP algorithms and risk scores. For example, several state PDMPs track the anticonvulsant drug gabapentin,[217] which is approved by the FDA to treat

211. *Id.* at 15.

212. *See, e.g.*, McElfresh et al., *supra* note 124, at 1742 (stating that "PDMP data directly influence clinicians' treatment decisions"); Picco et al., *supra* note 210, at 1 ("PDMP use influenced healthcare providers' clinical decision-making, resulting in both intended and unintended outcomes for patients. PDMPs are a public health initiative designed to reduce harms associated with increased opioid prescribing, yet their use is associated with multiple unintended outcomes."). *See generally*, Yuhua Bao, Yijun Pan, Aryn Taylor, Sharmini Radakrishnan, Feijun Luo, Harold Alan Pincus & Bruce R. Schackman, *Prescription Drug Monitoring Programs are Associated with Sustained Reductions in Opioid Prescribing by Physicians*, 35 HEALTH AFFS. 1045 (2016) (finding that PDMPs are associated with a greater than thirty percent decrease in Schedule II opioid prescriptions).

213. Picco et al., *supra* note 210, at 15.

214. *Id.*

215. Letter from Karen A. Miotto, President, Cal. Soc'y of Addiction Med., to Austin Weaver, Manager, Cal. Dep't of Just. CURES Program (Mar. 28, 2022), https://csam-asam.org/wp-content/uploads/2022-03-28-CSAM-President-Letter-to-CURES-DOJ-re-NarxCare.pdf [https://perma.cc/Y8ZB-6MUT].

216. *Id.*

217. *See, e.g.*, OHIO ADMIN. CODE § 4729:8-2-02(A) (2019) (titled "[a]dditional drugs to be reported" to the Ohio PDMP and including "[a]ll dangerous drug products containing gabapentin");

seizure disorders and postherpetic neuralgia (lasting, burning pain in the nerves and skin after shingles).[218] Gabapentin also is prescribed to treat chronic pain for individuals with disabling fibromyalgia, endometriosis, or chronic migraine.[219] Although it is not a federally controlled substance, concerns have been raised regarding gabapentin misuse, often in conjunction with opioids.[220] In states that surveil gabapentin through their PDMPs as either a state-designated controlled substance or a "drug of concern," health care providers may hesitate to prescribe the drug to chronic pain patients and, therefore, resort to less effective pain management treatments.

As the gabapentin example suggests, uncritical reliance on PDMP algorithmic information imposes incalculable harms on individuals with disabilities (other than SUD) and other conditions that cause chronic pain.[221] Many of these patients who had long been stable on or benefitted from a treatment regime that involved prescription opioid analgesics found themselves suddenly subject to involuntary tapers and medication discontinuation.[222] This was a result of the implementation of myriad laws and policies that forced or incentivized physicians and pharmacists to reduce or eliminate their opioid

OR. HEALTH AUTH., DATA SUBMISSION GUIDE FOR DISPENSERS: PRESCRIPTION DRUG MONITORING PROGRAM 2 (2024) ("As of January 1, 2020, gabapentin will change to a covered substance for the OR PDMP. Dispensers are required to report dispensations of gabapentin to the OR PDMP no later than 72 hours after a covered substance is dispensed and for each covered substance dispensed."); *see also* Alyssa M. Peckham, Maria J. Ananickal & David A. Sclar, *Gabapentin Use, Abuse, and the US Opioid Epidemic: The Case for Reclassification as a Controlled Substance and the Need for Pharmacovigilance*, 11 RISK MGMT. HEALTHCARE POL'Y 109, 111 fig.1 (2018) (providing a map of state PDMPs that surveil gabapentin as of 2018).

218. *Gabapentin*, CLEVELAND CLINIC (July 1, 2021), https://my.clevelandclinic.org/health/drugs/21561-gabapentin [https://perma.cc/2Z74-B29Z].

219. Amanda Workman, *Endometriosis and Fibromyalgia: Dual Treatments*, ENDOMETRIOSIS.NET (Jan. 29, 2021), https://endometriosis.net/living/treatment-fibromyalgia [https://perma.cc/T626-VLVS] ("Some examples of anticonvulsants used for endometriosis and fibromyalgia include Lyrica and gabapentin."); Michael D. Perloff, Rachel K. Berlin, Marshall Gillette, Matthew J. Petersile & Donna Kurowski, *Gabapentin in Headache Disorders: What Is the Evidence?*, 17 PAIN MED. 162, 162 (2016) (explaining that gabapentin "is more commonly used in the treatment of pain, including headache disorders" than as an antiepileptic).

220. Bridget M. Kuehn, *Growing Role of Gabapentin in Opioid-Related Overdoses Highlights Misuse Potential and Off-Label Prescribing Practices*, 328 JAMA 1283, 1283 (2022) (explaining that "[g]rowing evidence of misuse and overdoses involving gabapentin—often in conjunction with opioids—is drawing attention to substantial off-label prescribing of the anticonvulsant drug").

221. Buonora et al., *Paths Forward*, *supra* note 10, at 859–60; *see also* S. Michaela Rikard, Andrea E. Strahan, Kristine M. Schmit & Gery P. Guy Jr., *Chronic Pain Among Adults—United States, 2019–2021*, 72 MORBIDITY & MORTALITY WEEKLY REP. 379, 381 (2023) ("Chronic pain is a debilitating condition that affects the lives of millions of adults in the United States. During 2021, an estimated 20.9% of U.S. adults experienced chronic pain, similar to the reported estimate of 20.4% in 2016.").

222. Kate M. Nicholson, *Undoing Harm in Chronic Pain and Opioid Prescribing*, 112 AM. J. PUB. HEALTH SUPPLEMENT 1 S18, S18 (2022) (providing that policies intended to dramatically reduce opioid prescribing, such as the Centers for Disease Control prescribing guidelines, caused "[p]atients who had been stable on opioids [to be] tapered down or off their medication in ways that endangered their health and lives").

prescribing and dispensing practices.[223] Others were abandoned by their providers and continue to struggle to find access to treatment for their chronic pain conditions as their health and quality of life deteriorates.[224] A recent investigative report pointed out that "some 43 percent of US medical clinics now refuse to see new patients who require opioids."[225]

Experts have repeatedly emphasized that abrupt opioid therapy discontinuation and rapid, forced medication tapers are medically and ethically inappropriate and, therefore, violate the standard of care.[226] These dangerous practices often result in dire consequences for legacy opioid patients, ranging from "debilitating pain and suffering to severe depression and suicidal ideation to hospitalization and death."[227] An international coalition of pain experts, which self-identified as "deeply concerned about forced opioid tapering in patients receiving long-term prescription opioid therapy for chronic pain," published a letter in a leading pain journal contending that forcing chronic pain patients to taper from their opioid therapies was likely to motivate them to

223. *Id.*; Oliva, *Dosing Discrimination*, *supra* note 13, at 106 (noting that "[t]he significant risks associated with rapid, aggressive taper and discontinuation of patients on 'high doses' of opioids . . . are well documented" and "range from debilitating pain and suffering to severe depression and suicidal ideation to hospitalization and death"); HUM. RTS. WATCH, "NOT ALLOWED TO BE COMPASSIONATE": CHRONIC PAIN, THE OVERDOSE CRISIS, AND UNINTENDED HARMS IN THE US 3 (2018) (explaining that "federal and state governments have made reducing opioid prescribing a major priority in the last five years" and that "the atmosphere around prescribing for chronic pain had become so fraught that physicians felt they must avoid opioid analgesics even in cases when it contradicted their view of what would provide the best care for their patients").

224. HUM. RTS. WATCH, *supra* note 223, at 3–4 (pointing out that the "desire to cut back on opioid prescribing translated to doctors tapering patients off their medications without patient consent, while in others it meant that physicians would no longer accept patients who had a history of needing high-dose opioids").

225. Szalavitz, *The Pain Was Unbearable*, *supra* note 53.

226. Stefan G. Kertesz, Ajay Manhapra & Adam J. Gordon, *Nonconsensual Dose Reduction Mandates are not Justified Clinically or Ethically: An Analysis*, 48 J.L. MED. & ETHICS 259, 261 (2020); U.S. FOOD & DRUG ADMIN., FDA IDENTIFIES HARM REPORTED FROM SUDDEN DISCONTINUATION OF OPIOID PAIN MEDICINES AND REQUIRES LABEL CHANGES TO GUIDE PRESCRIBERS ON GRADUAL, INDIVIDUALIZED TAPERING (2019), https://www.fda.gov/drugs/drug-safety-and-availability/fda-identifies-harm-reported-sudden-discontinuation-opioid-pain-medicines-and-requires-label-changes [https://perma.cc/7TT7-WN7B (staff-uploaded archive)].

227. Oliva, *Dosing Discrimination*, *supra* note 13, at 106; *see also* Nicholson, *supra* note 222, at S18 (explaining that "opioid tapering may actually increase patients' risk of death, in addition to destabilizing their health, mental health, and lives"); Szalavitz, *Major Culprit*, *supra* note 46, at 27, 29 (contending that "[o]ne study of millions of medical records, which compared the timing of state opioid regulations and reductions and could therefore suggest causality, found that opioid reductions actually led directly to increased disability, decreased productivity, rising medical costs and more pain. Another study found that among veterans who had their opioids stopped involuntarily, 9 percent became suicidal and 2 percent actually tried to take their own lives"); HUM. RTS. WATCH, *supra* note 223, at 4 (noting that patients "were often left with debilitating pain that made them incapable of going about their daily lives — simple activities, such as household chores or taking care of others, were suddenly impossible. In many cases, patients suffered extreme anxiety and others even thoughts of suicide, as they questioned whether their lives would ever be worth living in such extreme pain.").

"seek relief from illicit (and inherently more dangerous) sources of opioids, whereas others may become acutely suicidal."[228] Those experts turned out to be correct. "[R]esearch shows that rather than minimizing overdose risk, cutting access to medical opioids nearly triples the odds of overdose death among people in pain."[229]

As is often the case in the American healthcare delivery system, the harms and negative health outcomes described above have been borne unequally across patient populations. Female and Black patients with chronic pain have been disproportionately impacted by the health harms associated with forced prescription drug tapers and opioid medication discontinuation.[230] There is a long of history of discrimination against Black and female patients in pain assessment and management due to entrenched but false stereotypes that medical experts attribute to these groups.[231]

Women suffering from pain are underassessed, undertreated, and discounted by medical providers.[232] Studies demonstrate that (1) women who

228. Beth D. Darnall, et al., *International Stakeholder Community of Pain Experts and Leaders Call for an Urgent Action on Forced Opioid Tapering*, 20 PAIN MED. 429, 429–30 (2019).

229. Szalavitz, *Major Culprit*, *supra* note 46, at 27, 29 (citing Jocelyn R. James, JoAnna M. Scott, Jared W. Klein, Sara Jackson, Christy McKinney, Matthew Novack, Lisa Chew & Joseph O. Merrill, *Mortality After Discontinuation of Primary Care-Based Chronic Opioid Therapy for Pain: A Retrospective Cohort Study*, 34 J. GEN. INTERNAL MED. 2749, 2752–53 (2019)).

230. Oliva, *Dosing Discrimination*, *supra* note 13, at 92–97.

231. *See, e.g.*, Kelly M. Hoffman, Sophie Trawalter, Jordan R. Axt & M. Norman Oliver, *Racial Bias in Pain Assessment and Treatment Recommendations, and False Beliefs About Biological Differences Between Blacks and Whites*, 113 PROCS. NAT'L ACAD. SCIS. 4296, 4296 (2016); Diana J. Burgess, David B. Nelson, Amy A. Gravely, Matthew J. Bair, Robert D. Kerns, Diana M. Higgins, Michelle van Ryn, Melissa Farmer & Melissa R. Partin, *Racial Differences in Prescription of Opioid Analgesics for Chronic Noncancer Pain in a National Sample of Veterans*, 15 J. PAIN 447, 447 (2014); COMM. ON UNDERSTANDING & ELIMINATING RACIAL & ETHNIC DISPARITIES IN HEALTH CARE, BD. ON HEALTH SCIS. POL'Y, INST. OF MED. OF THE NAT'L ACADS., UNEQUAL TREATMENT: CONFRONTING RACE AND ETHNIC DISPARITIES IN HEALTH CARE 1 (Brian D. Smedley, Adrienne Y. Stith & Alan R. Nelson eds., 2013); Ronald Wyatt, *Pain and Ethnicity*, 15 AMA J. ETHICS 449, 449 (2013); Vickie L. Shavers, Alexis Bakos & Vanessa B. Sheppard, *Race, Ethnicity, and Pain Among the U.S. Adult Population*, 21 J. HEALTH CARE FOR POOR & UNDERSERVED 177, 177 (2010); Karen O. Anderson, Carmen R. Green & Richard Payne, *Racial and Ethnic Disparities in Pain: Causes and Consequences of Unequal Care*, 10 J. PAIN 1187, 1187 (2009).

232. *See, e.g.*, Andis Robeznieks, *Women Bear Greater Burden of Opioid Epidemic*, AM. MED. ASS'N (June 27, 2017), https://www.ama-assn.org/delivering-care/opioids/women-bear-greater-burden-opioid-epidemic [https://perma.cc/8VL9-GACK]; Jennifer Billock, *Pain Bias: The Health Inequality Rarely Discussed*, BBC (May 22, 2018), https://www.bbc.com/future/article/20180518-the-inequality-in-how-women-are-treated-for-pain [https://perma.cc/Q7JN-H32X]; Carolyn M. Mazure & David A. Fiellin, *Women and Opioids: Something Different is Happening Here*, 392 LANCET 9, 9–10 (2018); Laura Kiesel, *Women and Pain: Disparities in Experience and Treatment*, HARV. HEALTH PUBL'G: HARV. HEALTH BLOG (Oct. 9, 2017), https://www.health.harvard.edu/blog/women-and-pain-disparities-in-experience-and-treatment-2017100912562 [https://perma.cc/A6AG-34HJ]; Joe Fasslerik, *How Doctors Take Women's Pain Less Seriously*, ATLANTIC (Oct. 15, 2015), https://www.theatlantic.com/health/archive/2015/10/emergencyroom-wait-times-sexism/410515/ [https://perma.cc/HT33-E7E5 (staff-uploaded, dark archive)].

are in acute pain are less likely than men to be prescribed analgesics by the emergency department,[233] (2) women who are prescribed analgesics are required to wait longer than men to receive those medications,[234] and (3) women who report pain are less likely than men to be believed by their clinicians.[235] Women also are "more likely to receive psychotropic medication for pain . . . and more likely to have pain attributed to emotional/psychological factors" than men.[236] Consistent with these findings, a recent study concluded that prescribers are more likely to rapidly taper women from prescription opioid therapy.[237] This dynamic is particularly startling given that men are more likely than women to misuse opioids and are twice as likely to experience a fatal overdose.[238]

Medical providers also systematically underassess and undertreat pain in patients racialized as Black.[239] Scholars attribute these disparities to medical practitioners' faith in centuries-old myths about Black biological exceptionalism that were generated to promote slavery and slave breeding.[240] Such false beliefs harbored by medical experts include, among other things, that Black people have less sensitive nerve endings, thicker skin, faster-coagulating blood, and stronger immune systems than their white counterparts.[241] Consequently, pain

233. Esther H. Chen, Frances S. Shofer, Anthony J. Dean, Judd E. Hollander, William G. Baxt, Jennifer L. Robey, Keara L. Sease & Angela M. Mills, *Gender Disparity in Analgesic Treatment of Emergency Department Patients with Acute Abdominal Pain*, 15 ACAD. EMERGENCY MED. 414, 415 (2008).

234. Billock, *supra* note 232.

235. Diane E. Hoffmann & Anita J. Tarzian, *The Girl Who Cried Pain: A Bias Against Women in the Treatment of Pain*, 29 J.L. MED. & ETHICS 13, 17–18 (2001).

236. Jaylyn Clark & Michael E. Robinson, *The Influence of Patient Race, Sex, Pain-Related Body Postures, and Anxiety Status on Pain Management: A Virtual Human Technology Investigation*, 12 J. PAIN RSCH. 2637, 2638 (2019). "The phrase 'psychotropic drugs' is a technical term for psychiatric medicines that alter chemical levels in the brain which impact mood and behavior." Enjoli Francis, *What You Need to Know About Psychotropic Drugs*, ABC NEWS (Dec. 2, 2011), https://abcnews.go.com/blogs/health/2011/12/02/what-you-need-to-know-about-psychotropic-drugs [https://perma.cc/6NT5-98PP].

237. Michele Buonora, Hector R. Perez, Moonseong Heo, Chinazo O. Cunningham & Joanna L. Starrels, *Race and Gender Are Associated with Opioid Dose Reduction Among Patients on Chronic Opioid Therapy*, 20 PAIN MED. 1519, 1524 (2019).

238. Joshua J. Fenton, Alicia L. Agnoli, Guibo Xing, Lillian Hang, Aylin E. Altan, Daniel J Tancredi, Anthony Jerant & Elizabeth Magnan, *Trends and Rapidity of Dose Tapering Among Patients Prescribed Long-Term Opioid Therapy, 2008–2017*, 2 JAMA NETWORK OPEN 1, 8 (2019).

239. *See, e.g.*, Janice A. Sabin, *How We Fail Black Patients in Pain*, AM. ASS'N OF MED. COLLS. (Jan. 6, 2020), https://www.aamc.org/news/how-we-fail-black-patients-pain [https://perma.cc/Q8LD-SBPS (staff-uploaded archive)] (concluding that "false ideas about black peoples' experience of pain can lead to worrisome treatment disparities"); Hoffman et al., *supra* note 231, at 4296; Burgess et al., *supra* note 231, at 448; COMM. ON UNDERSTANDING & ELIMINATING RACIAL & ETHNIC DISPARITIES IN HEALTH CARE, *supra* note 231, at 1; Wyatt, *supra* note 231, at 449; Shavers et al., *supra* note 231, at 179; Anderson et al., *supra* note 231, at 1198; Knox H. Todd, Christi Deaton, Anne P. D'Amado & Leon Goe, *Ethnicity and Analgesic Practice*, 35 ANNALS EMERGENCY MED. 11, 11 (2000).

240. Hoffman et al., *supra* note 231, at 4296.

241. *Id.* at 4298.

patients racialized as Black are less likely than similarly situated white patients to be prescribed analgesics to treat moderate to severe pain, and, even when they are prescribed opioids, they receive a lower dose than white patients with identical medical conditions.[242] Racial disparities in pain assessment and treatment are so pervasive and deeply-entrenched that they extend to Black children suffering from acute health conditions in the emergency care setting.[243]

These preexisting pain treatment-related racial disparities and biases have real world consequences for chronic pain patients and long-term opioid patients who are racialized as Black. Studies centered around such patients document that they are subject to "more frequent urinary drug monitoring" and "higher rates of opioid discontinuation when urine test results reveal illicit drugs" than white patients.[244] Replicating the above described gender disparities that attend to chronic pain patients on opioid therapy, clinicians also are more likely to force taper long-term opioid patients who are Black than those who are white.[245]

Multiple biases, assumptions, and stereotypes play a role in a provider's refusal to prescribe and treat vulnerable people and populations. In addition, as others have discussed, the reaction of clinicians to PDMP surveillance is hardly surprising given their reasonable desire to protect their liberty, livelihood, and licensure by avoiding law enforcement and professional regulatory board investigations.[246] A recent qualitative study of opioid prescriber behavior in West Virginia concluded that

> disciplinary action against [opioid] prescribers resulted in fear amongst other prescribers and affected their prescribing habits, overpowering

242. *Id.* at 4296 ("Extant research has shown that, relative to white patients, black patients are less likely to be given pain medications and, if given pain medications, they receive lower quantities"); *see also* Todd et al., *supra* note 239, at 11 ("White patients were significantly more likely than black patients to receive ED analgesics (74% versus 57% . . .) despite similar records of pain complaints in the medical record. The risk of receiving no analgesic while in the ED was 66% greater for black patients than for white patients."); Charles S. Cleeland, René Gonin, Luis Baez, Patrick Loehrer & Kishan J. Pandya, *Pain and Treatment of Pain in Minority Patients with Cancer*, 127 ANNALS INTERNAL MED. 813, 815 (1997) (finding that only thirty-five percent of racial minorities with metastatic or recurrent cancer received appropriate analgesia prescriptions compared with fifty percent for non-minority patients).

243. Monika K. Goyal, Nathan Kuppermann, Sean D. Cleary, Stephen J. Teach & James M. Chamberlain, *Racial Disparities in Pain Management of Children with Appendicitis in Emergency Departments*, 169 JAMA PEDIATRICS 996, 999 (2015) ("Black children with appendicitis were less likely to receive opioid analgesia than white children (12.2% . . . vs. 33.9% . . . , respectively.")).

244. Fenton et al., *supra* note 238.

245. Buonora et al., *Race and Gender*, *supra* note 237, at 1524.

246. *See, e.g.*, Kelly K. Dineen & James M. Dubois, *Between a Rock and a Hard Place: Can Physicians Prescribe Opioids To Treat Pain Adequately While Avoiding Legal Sanction?*, 42 AM. J.L. & MED. 7, 8–9 (2016). "A substantial number of [state medical board] actions involve misuse and misprescribing of controlled substances, including opioid misprescribing." *Id.* at 24 "An investigation alone can be devastating and a finding of liability can trigger a cascade of consequences that make it impossible to practice medicine." *Id.* at 22; *see also* Sessi Kuwabara Blanchard, *How Fear, Misinformation, Stigma Have*

> other considerations in decisions regarding prescribing. This fear was expressed by multiple participants and consequences included licensure revocation or criminal penalties related to opioid prescribing which the prescriber feared would be seen as excessive or inappropriate, even if they deemed it medically necessary.[247]

Consistent with these findings, Dr. Stephen Kertesz, a professor of medicine and public health at the University of Alabama-Birmingham, has noted that

> [t]he problem that really infuses the NarxCare discussion is that the environment in which it is being used has an intense element of law enforcement, fear, and distrust of patients . . . . It's added to an environment where physicians are deeply fearful for their future ability to maintain a profession, where society has taken a particularly vindictive turn against both physicians and patients. And where the company that develops this interesting tool is able to force it onto the screens of nearly every doctor in America.[248]

In sum, "[f]or over a decade, the DEA and attorneys general have ramped up investigations of practitioners, pharmacists and distributors," and, consequently, "[t]he fear of law enforcement in chilling prescriptions cannot be overstated."[249]

Providers and institutions that refuse to prescribe for or treat patients indicated for prescription opioids for their SUD, chronic pain conditions, or other disabilities may rationalize their decisions based on a belief that such patients are better treated elsewhere. As a recent study that centered the perspectives of primary and specialty care physicians on caring for people with disabilities noted:

> Some physicians described their thought processes in these situations, sometimes acknowledging that they were aware of requirements that prevented them from denying care because of disability. As one specialist put it, "I think the problem is that you cannot refuse them straight. We

Devastated US Pain Patients, FILTER MAG. (Apr. 28, 2021), https://filtermag.org/pain-patients-opioids-fear [https://perma.cc/2MDH-GVMU]; Sara Ray & Kathleen Hoffman, *Opioid Stigma is Keeping Many Cancer Patients from Getting the Pain Control They Need*, STAT NEWS (July 6, 2018), https://www.statnews.com/2018/07/06/cancer-patients-pain-opioid-stigma/ [https://perma.cc/UK3P-3U7X].

247. Cara L. Sedney, Treah Haggerty, Patricia Dekeseredy, Divine Nwafor, Martina Angela Caretta, Henry H. Brownstein & Robin A. Pollini, *"The DEA Would Come in and Destroy You": A Qualitative Study of Fear and Unintended Consequences Among Opioid Prescribers in WV*, 17 SUBSTANCE ABUSE TREATMENT PREVENTION & POL'Y 1, 4 (2022).

248. Szalavitz, *The Pain Was Unbearable*, *supra* note 53.

249. Blanchard, *supra* note 246.

> have to give them an appointment. You have to come up with a solution that this is a small facility, we are not doing justice to you, it is better you would be taken care of in a special facility."[250]

The study also found that many physicians expressed explicit bias toward people with disabilities and described strategies for discharging them from their practices.[251]

Whether offered in good faith or as a pretext for excluding patients on the basis of disability, such a justification, without more, is not sufficient under disability antidiscrimination law. In the landmark 1999 case *Olmstead v. L.C.*,[252] the Supreme Court relied on the "integration mandate" in the federal regulations implemented pursuant to Title II of the ADA, which requires public entities to "administer services, programs, and activities in the most integrated setting appropriate to the needs of qualified individuals with disabilities."[253] Those regulations define the "most integrated setting" as one that "enables individuals with disabilities to interact with nondisabled persons to the fullest extent possible . . . ."[254] The ADA's community integration mandate requires health care providers and entities to provide medical care to patients with SUD in the most integrated setting possible appropriate to those patients' individual needs.[255] It does not stand for the proposition that patients with SUD, or those who are being treated with medication for SUD, or those who are being treated with surveilled controlled substances for stigmatized chronic pain conditions ought to receive their care in a "separate" or "specialized" facility purportedly more suitable to their needs.[256]

Simply stated, the robust and growing body of literature discussed above demonstrates that overreliance on information from PDMP algorithms and their associated patient risk scores drives individual provider and institutional refusals to prescribe and treat vulnerable people based on actual, perceived, or past SUD. Disability antidiscrimination laws can be engaged to challenge these categorical refusals to prescribe or treat. As described in the next section, disability antidiscrimination laws also have the potential to address the deeply rooted stereotypes and assumptions that underlie this pervasive and harmful behavior.

250. Tara Lagu, Carol Haywood, Kimberly Reimold, Christene DeJong, Robin Walker Sterling & Lisa I. Iezzoni, *'I Am Not the Doctor for You': Physicians' Attitudes About Caring for People with Disabilities*, 41 HEALTH AFFS. 1387, 1392 (2022).

251. *Id.*

252. Olmstead v. L.C. *ex rel.* Zimring, 527 U.S. 581 (1999).

253. *Id.* at 592.

254. Integrated Settings, 28 C.F.R. § 36.203(a) (1992); Prohibition of Discrimination by Public Accommodations, 42 U.S.C. § 12182 (b)(1)(B) (1992).

255. *See, e.g.*, Lagu et al., *supra* note 250, at 1391–92.

256. *Id.*

B. *Lack of Individualized Assessment*

Access to PDMP data in health care is pervasive, and overreliance on PDMP algorithmic information in clinical settings risks replacing or overshadowing an individualized clinical assessment of the patient's particular circumstances and needs. Numerous skilled nursing facilities, for example, routinely deny admission to all individuals who are being treated for SUD with medication as a matter of policy.[257] According to a charge settled by DOJ in 2020, one chain of skilled nursing facilities refused to admit otherwise qualified patients on over 350 occasions.[258] Similarly, and as discussed above, although PDMP algorithmic information should not be the sole driver of clinical decision-making, clinical decisions are too often based primarily on PDMP information to the detriment of vulnerable patients.

Disability antidiscrimination laws have the potential to disrupt overreliance on algorithmic information that leads to the exclusion, abandonment of, or failure to appropriately treat people with SUD or other disabilities. The COVID-19 pandemic highlighted concerns regarding the use of clinical algorithms to distribute scarce medical resources in a manner that disadvantaged individuals with disabilities.[259] In the midst of the pandemic in March 2020, the OCR issued a bulletin to clarify that Section 504 of the Rehabilitation Act and ACA Section 1557 prohibit the denial of medical care to people with disabilities on the basis of "stereotypes, assessments of quality of life," and "judgments about a person's relative 'worth' based on the presence or absence of disabilities or age."[260] Instead, decisions concerning whether an individual is a viable candidate for treatment should be "based on an individualized assessment of the patient based on the best available objective

257. *See, e.g.*, Dec. 29, 2020 Press Release, *supra* note 162; U.S. DEP'T OF JUST., DJ No. 202-36-308, SETTLEMENT AGREEMENT BETWEEN THE UNITED STATES OF AMERICA AND ATHENA HEALTH CARE SYSTEMS UNDER THE AMERICANS WITH DISABILITIES ACT (2019), https://archive.ada.gov/athena_healthcare_sa.html [https://perma.cc/T8A6-ZY64]; May 10, 2018 Press Release, *supra* note 206.

258. Dec. 29, 2020 Press Release, *supra* note 162.

259. *See generally*, NAT'L COUNCIL ON DISABILITIES, THE IMPACT OF COVID-19 ON PEOPLE WITH DISABILITIES (Oct. 29, 2021), https://ncd.gov/sites/default/files/NCD_COVID-19_Progress_Report_508.pdf [https://perma.cc/5KWA-LWDA] (finding that people with intellectual or developmental disabilities, and medically fragile and technology dependent individuals, faced a high risk of being triaged out of COVID-19 treatment when hospital beds, supplies, and personnel were scarce).

260. HHS OFF. FOR C.R., BULL.: CIVIL RIGHTS, HIPAA, AND THE CORONAVIRUS DISEASE 2019 (COVID-19) 1 (2020).

medical evidence."[261] HHS reiterated this requirement in its 2022 Section 1557 proposed rule in the context of algorithmic discrimination:

> Covered entities using clinical algorithms in their decision-making should consider clinical algorithms as a tool that supplements their decision-making, rather than as a replacement of their clinical judgment. By over-relying on a clinical algorithm in their decision-making, such as by replacing or substituting their own clinical judgment with a clinical algorithm, a covered entity may risk violating Section 1557 if their decision rests upon or results in discrimination.[262]

Disability antidiscrimination laws also have the potential to interrupt overreliance on PDMP algorithmic information and deeply rooted biases and stereotypes about people associated with highly stigmatized prescription medications tracked by PDMPs because they mandate an individualized assessment and proscribe the imposition of blanket policies and rigid cut-offs. For example, an orthopedic surgery center concerned about managing post-operative pain for a patient being treated with medication for SUD[263] should base its clinical judgment on the specific needs and medical history of the patient in concert with a consultation with the physician treating the patient for SUD, rather than simply refuse to treat the patient based on their PDMP risk scores, SUD medication treatment, or both.

The individualized assessment mandate also serves as a mechanism to address serious errors, omissions, and biases that find their way into PDMP algorithms and the risk scores they generate. As previously explained, there is a dearth of evidence demonstrating the clinical value of PDMP algorithms, and it is unclear if the critiques of PDMP algorithms and their risk scores will be addressed by federal regulators.[264] That stated, clinical overreliance on PDMP algorithmic information can result in disability discrimination even if PDMP algorithms have proven clinical value.

As a clinical decision-making tool, PDMP algorithmic information is shockingly incomplete. As mentioned above, neither the NarxCare risk scoring platform nor PDMP databases collect or evaluate patient diagnoses or other health care conditions.[265] As a result, the NarxCare risk scoring algorithms treat terminal cancer patients, who are necessarily indicated for analgesic treatment,

261. *Id.*

262. Nondiscrimination in Health Programs and Activities, 87 Fed. Reg. 47824, 47840 (proposed Aug. 4, 2022) (to be codified at 45 C.F.R. pt. 92.210); *see also* Nondiscrimination in Health Programs and Activities, 89 Fed. Reg. 37522, 37650 (May 6, 2024) (to be codified at 45 C.F.R. pt. 92.210).

263. May 20, 2021 Press Release, *supra* note 162.

264. *See supra* Section I.D.

265. Oliva, *Dosing Discrimination*, *supra* note 13, at 88; Szalavitz, *The Pain Was Unbearable*, *supra* note 53 (reporting that Bamboo Health "told WIRED that NarxCare and its scores 'do not include any diagnosis information' from patient medical records").

the same as patients with any other health care condition. Similarly, the risk scoring algorithm treats as identical a patient *who is being treated with opioid medication for SUD effectively under the supervision of a qualified physician* and a patient who is taking opioid medication for any other health care condition in the absence of any evidence that the individual has been screened or received treatment for SUD. PDMPs also fail to capture information concerning various factors that may increase health risks for some patients, such as polysubstance drug use involving drugs not tracked by the PDMP (i.e., alcohol or illicit drugs).

Individualized assessment is especially important in the company of decision support algorithms, like those deployed by NarxCare, that lack external validation for their intended use, clinical use, or both. As noted in a 2023 study of NarxCare and a similar tool used by the Veterans Health Administration ("the NarxCare/STORM study"), without sufficient validation, PDMP information and the risk scores generated by PDMP software platforms can mislead providers and directly harm patients:

> In the context of the opioid epidemic, an improperly validated [scoring] system can have severe consequences. For example, if the NarxCare model leads a pharmacist to believe that a patient's risk of overdose is higher than their actual risk, the pharmacist may decline to fill the patient's prescription, disrupting their treatment plan. This can leave the patient frustrated and with potentially disabling pain . . . . A model can also suggest that a patient's risk is lower than their actual risk and miss an opportunity to prevent opioid misuse or a lethal overdose.[266]

Other critical omissions from PDMP data reflect the failings of the larger public narrative around the "opioid epidemic." Like much public discourse deployed to explain challenging, multi-dimensional social, economic, and political problems, the narrative is overly simplistic and ahistorical and, therefore, excludes from examination many of the long-standing, complex, demand-side causal factors in play in our ongoing drug poisoning crisis.[267] Such factors include, but are not limited to, widespread despair and alienation, social and economic inequality, unemployment, and the lack of access to affordable housing, healthcare, nutrition, and adequate community supports.[268] The failure

266. McElfresh et al., *supra* note 124, at 1743.

267. NANCY D. CAMPBELL, NALOXONE AND THE POLITICS OF OVERDOSE 23 (2020) (stating that "[n]either overdose nor its remedy is simple or straightforward"); Jalali et al., *supra* note 45, at 2 (providing that "[t]he complexity of the [drug poisoning] crisis is represented by the multiple spheres of influence derived from individual factors, interpersonal relationships, and community and societal influences, indicating the necessity of a broader and a more integrated approach that includes prevention, treatment and overdose rescue interventions in addition to supply reduction strategies").

268. *See* Hawre Jalal & Donald S. Burke, *Exponential Growth of Drug Overdose Poisoning and Opportunities for Intervention*, 117 ADDICTION 1200, 1200 (2022) (noting that "[s]ome research

to properly define a complicated, multi-causal problem like the drug poisoning crisis significantly limits our ability to respond to it with effective, evidence-based solutions.[269] Individualized patient assessments derived from the best available objective medical evidence can counter these complications. This is because such assessments give health care providers a meaningful opportunity to address critical gaps in PDMP data and consider other pertinent information about patients who use the medications tracked by PDMPs.

C. *Unsupported Safety Concerns*

Biases and false beliefs regarding drug use by disfavored groups and their alleged "dangerousness" are also at play in prescribing decisions as evidenced by the opioid narrative's persistent framing of its "victims" as rural and suburban middle-class white communities.[270] American "drug narratives [typically] associate the most vilified substances with minoritized populations, who have been caricatured as moral deviants hijacked by an uncontrollable urge to give in to sinful pleasures of a 'high,' no matter the cost."[271] These sort of causal tales enable the state to criminalize and harshly punish the disfavored outgroups it associates with "bad" drugs with robust support from the public

[regarding drug poisoning death causality] points to demand-side factors, such as increased economic inequalities, deteriorating employment opportunities, [and a] heightened sense of despair and alienation"); Kara E. Rudolph, Elizabeth N. Kinnard, Ariadne Rivera Aguirre, Dana E. Goin, Jonathan Feelemyer, David Fink & Magdelena Cerda, *The Relative Economy and Drug Overdose Deaths*, 31 EPIDEMIOLOGY 551, 556 (2020) (finding "evidence for associations between aspects of economic opportunity . . . and drug overdose mortality at the county level"); *see also* Carol Graham, *America's Crisis of Despair: A Federal Task Force for Economic Recovery and Societal Well-being*, BROOKINGS INST. (Feb. 10, 2021), https://www.brookings.edu/research/americas-crisis-of-despair-a-federal-task-force-for-economic-recovery-and-societal-well-being/ [https://perma.cc/98NN-PL5J].

269. Taleed El-Sabawi & Jennifer D. Oliva, *The Influence of White Exceptionalism on Drug War Discourse*, 94 TEMP. L. REV. 649, 650–51 (2022); Ron Schultz, *Adjacent Opportunities: The Failure of Simple Answers*, 12 EMERGENCE: COMPLEXITY & ORG. 81, 81 (2010) (explaining that "we have diluted our messages and with them our capability to address difficult solutions, because the answers we seek are supposed to be simple enough so the most simple among us can understand it" and "[w]hat this approach produces are increasingly complex failures").

270. *See generally* El-Sabawi & Oliva, *supra* note 269 (explaining that "rhetorical policy tactics" cause people to blame minority populations for the nationwide drug problem); Julie Netherland & Helena B. Hansen, *The War on Drugs That Wasn't: Wasted Whiteness, "Dirty Doctors," and Race in Media Coverage Prescription Opioid Misuse*, 40 CULT. MED. PSYCH. 664 (2016) (arguing that the difference in media coverage based on race "distinguish white from black (and brown) suffering"); Julie Netherland & Helena Hansen, *White Opioids: Pharmaceutical Race and the War on Drugs That Wasn't*, 12 BIOSOCIETIES 217 (2017) (discussing the dichotomy in the different policies utilized in black and brown versus white neighborhoods).

271. El-Sabawi & Oliva, *supra* note 269, at 649; *see also* Doris Marie Provine, *Race and Inequality in the War on Drugs*, 7 ANN. REV. L. SOC. SCI. 41, 42 (2011) ("Advocates have been able to make some drugs seem relatively benign by, for example, associating their use with college students. More often, however, the goal has been to establish harsh criminal sanctions for selected drugs. The most fruitful approach has been to link the drug with a disliked racial minority.").

irrespective of the substance's toxicological profile and risk-benefit analysis.[272] As one scholar has observed, "[t]he American public has proven receptive to scare stories about 'the dangerous classes.'"[273]

Consequently, health care providers may assume or contend that people with high PDMP scores represent a danger to themselves or others in a clinical setting.[274] The individualized assessment mandate also serves as a mechanism to address legitimate safety concerns. For example, an orthopedic surgery center may claim that it refused treatment based on concerns about managing post-operative pain for patients taking medication for SUD.[275] Although a health care entity may impose legitimate safety requirements necessary for effective operation, those requirements must be based on actual risks and not speculation, stereotypes, or generalizations about people with disabilities even if held in good faith.[276]

D. *Lack of Reasonable Modifications*

Finally, the ADA, the Rehabilitation Act, and Section 1557 require health care providers, systems, and institutions to make individualized, reasonable modifications to policies, practices, and procedures to ensure that people with disabilities have equal opportunities to benefit from health care programs, services, and facilities.[277] The 2022 Section 1557 proposed rule emphasizes that its algorithmic nondiscrimination requirements "put covered entities on notice that they cannot use discriminatory clinical algorithms and may need to make

272. El-Sabawi & Oliva, *supra* note 269, at 649–50.

273. Provine, *supra* note 271, at 42.

274. 42 U.S.C. § 12113(a)–(b), 42 U.S.C. § 12111(3); 29 C.F.R. § 1630.2(r) (defining "direct threat" as "significant risk of substantial harm to the health or safety of others" that cannot be eliminated or reduced by a reasonable accommodation).

275. May 20, 2021 Press Release, *supra* note 162.

276. Bragdon v. Abbott, 524 U.S. 624, 626–67 (1998); U.S. DEP'T OF JUST. C.R. DIV., TITLE III MANUAL, *supra* note 139, at 4–6; OCR, NORTH END REHABILITATION & HEALTHCARE CENTER, *supra* note 165, at 5. A 2023 agreement between the DOJ, the OCR, and a skilled nursing facility—providing clinical services, subacute rehab, chronic kidney disease management, a ventilator program, long term care, respite care, and urgent skilled nursing services and alleged to have denied admission to patients because they were prescribed medication for OUD—contained similar statements. *Id.* at 4. The Equal Employment Opportunity Commission guidance for employers and for health care providers on existing legal protections in the workplace for individuals who are using opioids or individuals with a current or former SUD place similar emphasis on these requirements. U.S. EQUAL EMP. OPPORTUNITY COMM'N, EEOC-NTVA-2020-2, USE OF CODEINE, OXYCODONE, AND OTHER OPIOIDS: INFORMATION FOR EMPLOYEES (2020); U.S. EQUAL EMP. OPPORTUNITY COMM'N, EEOC-NTVA-2020-1, HOW HEALTH CARE PROVIDERS CAN HELP CURRENT AND FORMER PATIENTS WHO HAVE USED OPIOIDS STAY EMPLOYED (2020).

277. General Prohibitions Against Discrimination, 28 C.F.R. § 35.130(b) (2016); Prohibition of Discrimination by Public Accommodations, 42 U.S.C. § 12182(b)(2)(A) (1990); Requirement to Make Reasonable Modifications, 45 C.F.R. § 92.105 (2022).

reasonable modifications in their use of the algorithms . . . ."[278] As the law makes clear, accommodation decisions should be collaborative, focus on the patient's specific needs, and take into account the patient's individual preferences and perspectives.[279] The 2024 final rule emphasizes this requirement with the example of a Crisis Standard of Care flowchart, a tool used to inform the allocation of scarce medical resources during a pervasive or catastrophic disaster such as the COVID-19 pandemic:

> Such a flowchart may result in discrimination if, for example, it screens out individuals with disabilities, prohibiting them from equally accessing a health care service, program, or activity that a covered entity offers by assessing an individual's potential response to life-saving care without making an individualized assessment of the individual's health *and without providing modifications for how an individual's disability or age could affect the assessment factors used in the algorithm or the time needed for the individual to respond to treatment*.[280]

Simply stated, disability antidiscrimination laws require health care providers and systems to extend individualized, reasonable accommodations to patients when using patient decision support tools in the clinical setting.

IV. RECOMMENDATIONS

This Article is not the first to critique PDMPs as law enforcement, public health, or clinical care tools. Scholars have raised important concerns regarding the narrow strategic focus of PDMPs, the selection and reliability of PDMP data points, the design of PDMP algorithms and patient risk scoring models,[281] the lack of external validation and demonstration of PDMP clinical value,[282] and the potential for PDMPs to result in health harms and exacerbate health inequities.[283] Critics frequently direct their solutions at the PDMP algorithm

278. Nondiscrimination in Health Programs and Activities, 87 Fed. Reg. 47824, 47880 (proposed Aug. 4, 2022) (to be codified at 45 C.F.R. pt. 92.210).

279. Title II entities are required to give primary consideration to patient preferences, while Title III entities are encouraged to consult patients and emphasize their needs. General, 28 C.F.R. § 35.160(b)(2) (2011); Auxiliary Aids and Services, 28 C.F.R. § 36.303(c)(2) (2017); *see also* U.S. DEP'T OF JUST. C.R. DIV., ADA REQUIREMENTS: EFFECTIVE COMMUNICATION (2020), https://www.ada.gov/effective-comm.htm [https://perma.cc/9YJY-FX2F].

280. Nondiscrimination in Health Programs and Activities, 89 Fed. Reg. 37522, 37644 (May 6, 2024) (to be codified at 45 C.F.R. pt. 92.210) (emphasis added).

281. *See, e.g.*, Oliva, *Dosing Discrimination*, *supra* note 13, at 89–102; Beletsky, *supra* note 135, at 141–42.

282. *See, e.g.*, McElfresh et al., *supra* note 124, at 3.

283. *See, e.g.*, Oliva, *Dosing Discrimination*, *supra* note 13, at 89–102; Erin P. Finley, Ashley Garcia, Kristen Rosen, Don McGeary, Mary Jo Pugh & Jennifer Sharpe Potter, *Evaluating the Impact of Prescription Drug Monitoring Program Implementation: A Scoping Review*, 17 BMC HEALTH SERVS. RSCH. 1, 4–8 (2017).

developers and software manufacturers by contending, among other things, that PDMP risk scoring platforms should be subject to FDA regulation under the federal Food, Drug, and Cosmetics Act[284] or, under new, proposed legislation, such as the Algorithmic Accountability Act.[285]

As noted in the 2024 Section 1557 final rule, federal departments and agencies are also taking action aimed at developers of clinical algorithms.[286] For example, the Office of the National Coordinator for Health Information Technology recently published a final rule for "Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing" aimed at clinical algorithm developers.[287]

We focus here on a different and complementary strategy: addressing the use of clinical algorithms and other patient care decision support tools by health care providers as an issue of equity and antidiscrimination, and specifically challenging PDMP algorithmic discrimination as disability discrimination. The 2024 final rule provides additional guidance regarding the application of existing antidiscrimination requirements to the use of clinical algorithms and other patient care decision support tools.[288] As such, it presents an opportunity to enhance existing antidiscrimination protections in health care for people with disabilities, including people who have, are perceived to have, or have a history of SUD or other disabilities and are harmed by clinical reliance on the risk scores generated by PDMP algorithms. This part offers recommendations to strengthen the final rule, harmonize new and existing antidiscrimination protections, and improve implementation and enforcement efforts. While these proposals focus on PDMP algorithmic discrimination, they are also intended to address the risk of discrimination resulting from the interpretation and use of information derived from a range of clinical algorithms in health care decision making.

A. *Final Rule Addressing Algorithmic Discrimination*

The 2024 Section 1557 final rule articulates two specific requirements on covered entities that use patient care decision support tools such as clinical algorithms. Section 92.210(b) requires a covered entity to make reasonable

284. *See, e.g.*, Oliva, *Dosing Discrimination*, *supra* note 13, at 107–15; Hoffman & Podgurski, *supra* note 202, at 37–38.

285. Hoffman & Podgurski, *supra* note 202, at 34–37.

286. Nondiscrimination in Health Programs and Activities, 89 Fed. Reg. 37522, 37644 (May 6, 2024) (to be codified at 45 C.F.R. pt. 92.210) (summarizing such federal department and agency activity).

287. *See* Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing, 89 Fed. Reg. 1192, 1192 (Jan. 9, 2024) (to be codified at 45 C.F.R. pts. 170, 171) (establishing new certification requirements for clinical algorithm developers); Nondiscrimination in Health Programs and Activities, 89 Fed. Reg. at 37643.

288. Nondiscrimination in Health Programs and Activities, 89 Fed. Reg. at 37645.

efforts to identify patient care decision support tools used in its health programs and activities that employ input variables or factors that measure race, color, national origin, sex, age, or disability. Section 92.210(c) requires that for each patient care decision support tool identified in paragraph (b), a covered entity must make reasonable efforts to mitigate the risk of discrimination resulting from the tool's use in its health programs or activities.[289] The final rule also emphasizes that covered entities must "exercise due diligence when acquiring and using [clinical algorithms] to ensure compliance with § 92.210."[290] While HHS declined to require specific mitigation efforts in favor of a more flexible approach, it did provide that OCR "will continue to consider additional actions to support covered entities in implementation and compliance consistent with Federal law, including guidance or engaging in future rulemaking."[291]

HHS should strengthen Section 92.210 of the 2024 final rule by promoting three additional requirements in future rulemaking or as strong recommendations in guidance to support covered entities in implementation and compliance. First, HHS should mandate or strongly encourage that health care providers and entities ensure that clinical algorithms work as intended and have clinical utility and validity as an essential form of due diligence methodology and risk mitigation efforts. As explained above, PDMP risk scoring algorithms have neither been externally validated by peer review nor the FDA[292] and researchers have raised serious questions about the validity of NarxCare scores.[293] The NarxCare/STORM study explains that both *technical validation*, whether the tool accurately and reliably predicts what it aims to predict—and *clinical validation*—whether the tool yields its intended impact on providers and patients, are critical to prevent serious patient harms.[294] As noted in the proposed Section 1557 rule, the American Medical Association has issued similar guidance regarding the evaluation, use, and monitoring of artificial intelligence systems and clinical algorithmic tools used in health care.[295]

As explained throughout this Article, PDMP algorithms are unlikely to clear these validation hurdles given the lack of evidence demonstrating that they accurately and reliably predict risk, improve clinical outcomes, or minimize health harms. It is nonetheless reasonable to anticipate that other clinical

289. *Id.* at 37651 (adding § 92.210(b), (c)).

290. *Id.* at 37647.

291. *Id.* at 37645.

292. Oliva, *Dosing Discrimination*, *supra* note 13, at 107–15; *see also* London, *supra* note 125 (noting that NarxCare "leverages a black box algorithm that has never been subject to outside or peer evaluation").

293. Kilby, *supra* note 126, at 10–11.

294. Nondiscrimination in Health Programs and Activities, 89 Fed. Reg. at 37648; McElfresh et al., *supra* note 124, at 2.

295. Nondiscrimination in Health Programs and Activities, 87 Fed. Reg. 47824, 47883 (proposed Aug. 4, 2022) (to be codified at 45 C.F.R. pt. 92.210).

algorithms, such as those specifically designed for clinical care rather than law enforcement surveillance, will be quite capable of achieving technical and clinical validation. As has been pointed out in the literature, FDA has the power to regulate PDMP algorithms under its Software as a Medical Device ("SaMD") authority and the agency has acknowledged the same in recent regulatory guidance.[296] Moreover, clinical validation sufficient to justify the use of clinical algorithms, including PDMP algorithms, can be achieved via peer review even in the absence of FDA approval or clearance of the software. In fact, the final rule outlines multiple sources of information available to covered entities regarding clinical algorithms and other patient care decision support tools including examples in the proposed and final rules, HHS information and advisories to the public, articles or research studies published in peer-reviewed medical journals, professional and hospital associations, media coverage, and from nonprofit organizations in the field of artificial intelligence.[297]

Second, HHS should require or more strongly advise that healthcare institutions develop publicly available standards for the use of clinical algorithms, including protocols that pertain to patient disclosure of PDMP data and algorithm-generated patient risk scores. Despite the potential benefits to patients, the final rule declined to require covered entities to notify patients about the clinical algorithms and other patient care decision support tools they use in their health programs and activities in light of "the possible frequent changes and the costs associated with notifying patients."[298] However, the final rule also notes that "it would be a best practice for covered entities to disclose information to patients about the patient care decision support tools used in their health programs and activities" and encourages covered entities to establish written policies and procedures as a form of risk mitigation under Section 92.210.[299]

The implementation of such protocols as best practices should be strongly encouraged, if not required. HHS should work with covered entities and other stakeholders to develop publicly available model protocols that reflect the range of antidiscrimination requirements of the ADA, Section 504, and Section 1557 that apply to the use of PDMPs and their risk scores, as well as the specific requirements of Section 1557 that apply to clinical algorithms and other patient care decision support tools. These protocols should provide clear notice to patients and instruction on how to request a reasonable accommodation regarding the use of PDMP information. Healthcare providers and health systems should also extend to patients an opportunity to review—and request corrections to—their PDMP records.

296. Oliva, *Dosing Discrimination*, *supra* note 13, at 107–15.
297. Nondiscrimination in Health Programs and Activities, 89 Fed. Reg. at 37647–48.
298. *Id.* at 37646.
299. *Id.*

Third, HHS should require covered providers and entities to prioritize the equitable use and impact of clinical algorithms and other patient care decision tools. The American Medical Association guidance identifies specific strategies to ensure equitable use by providers:

> Providers should . . . develop a clear protocol to identify and correct for potential bias, have the ability to override the tool, ensure meaningful oversight is in place for ongoing monitoring, and ensure clear protocols exist for enforcement and accountability, including a clear protocol to ensure equitable implementation. When evaluating a tool, a provider should ask whether the tool was properly validated and validated for the specific case and use, whether it was tested in different populations to identify hidden bias, and whether it allows barriers to access to be found and rectified, among other things.[300]

There is no question that the clinical interpretation and use of a decision support algorithm can result in discrimination and unequal treatment even where it has been established that the algorithm has technical and clinical value. For example, even assuming that PDMP algorithms can accurately predict a patient's risk for SUD, the question remains—are providers interpreting and using PDMP risk scores to provide appropriate treatment and do what is in the patient's best interest, or, to stigmatize, abandon, or exclude the patient? Regardless of provider intent, the pertinent issues are the health impacts that the clinical interpretation and use of the clinical PDMP algorithms have on people with actual, perceived, or past SUD or other disabilities. In that connection, the final Section 1557 rule acknowledges the growing body of research demonstrating that clinical algorithms often create or contribute to discrimination against marginalized communities.[301] As such, it is critically important that health care providers and systems actively monitor, protect, and promote the equitable use of such clinical decision-support tools on both individual and systemic levels.

B. *Robust Enforcement and Guidance*

Enhanced by the recommendations enumerated above, the ADA, Section 504 of the Rehabilitation Act, and Section 1557 have the potential to

300. Nondiscrimination in Health Programs and Activities, 87 Fed. Reg. at 47883.

301. Nondiscrimination in Health Programs and Activities, 89 Fed. Reg. at 37645 (citing Nondiscrimination in Health Programs and Activities, 87 Fed. Reg. at 47881–82); *see also* Michael P. Cary, Anna Zink, Sijia Wei, Andrew Olson, Mengying Yan, Rashaud Senior, Sophia Bessias, Kais Gadhoumi, Genevieve Jean-Pierre, Demy Wang, Leila S. Ledbetter, Nicoleta J. Economou-Zavlanos, Ziad Obermeyer & Michael J. Pencina, *Mitigating Racial and Ethnic Bias and Advancing Health Equity in Clinical Algorithms: A Scoping Review*, 42 HEALTH AFFS. 1359, 1365 (2023) ("Health equity should be fundamental to designing, evaluating, and deploying clinical algorithms in real-word clinical settings to ensure that their use does not result in discrimination.").

meaningfully address the extensive and health-harming clinical discrimination against people with (and those perceived to have) SUD and other disabilities based on PDMP algorithmic information. These enhanced disability antidiscrimination laws will fall short, however, unless their enforcement is robust and equitable.

Experts often claim that disability antidiscrimination laws are underenforced and, consequently, that their promises have gone unrealized, particularly in health care settings[302] and for people with SUD.[303] The DOJ and OCR have broad authority to investigate, mediate, litigate, and settle individual and class-based claims under these laws. As alluded to above, these agencies have increased enforcement activity aimed at protecting individuals with SUD, including in health care settings, over the last several years. Private individuals and groups also are entitled to bring disability discrimination actions pursuant to these laws, with certain limitations.[304]

Given the pervasive stigma, stereotypes, and false beliefs about disability, generally, and SUD in particular, successful enforcement efforts must be accompanied by effective education. Research demonstrates a lack of knowledge about, and noncompliance with, disability antidiscrimination laws in health care settings.[305] Recent studies reveal that many physicians know little to nothing about their legal responsibilities under the ADA,[306] including the statute's accommodation requirements.[307] One such study found that a notable number of physicians expressed explicit bias toward people with disabilities and described strategies for discharging them from their practices.[308] In the context of patients with SUD, a separate review of the literature concluded that twenty percent to fifty-one percent of health care providers had negative attitudes and

302. *See, e.g.*, NAT'L COUNCIL ON DISABILITIES, THE CURRENT STATE OF HEALTH CARE FOR PEOPLE WITH DISABILITIES 14–15 (2009) [hereinafter NAT'L COUNCIL ON DISABILITIES, CURRENT STATE].

303. Dineen & Pendo, *Engaging Disability Rights Law*, *supra* note 168, at 42–45.

304. *See, e.g.*, Ruth Colker, *The Americans with Disabilities Act's Unreasonable Focus on the Individual*, 170 U. PA. L. REV. 1813, 1813 (2022) ("[T]he requirement to claim status as an 'individual with a disability' to seek reasonable accommodations under the [ADA] undermines the advancement of structural reform that could promote broad conceptions of disability justice."); NAT'L COUNCIL ON DISABILITY, CUMMINGS V. PREMIER REHAB KELLER PLLC: IMPLICATIONS AND AVENUES FOR REFORM 1 (2023) (analyzing the Supreme Court decision in *Cummings v. Premier Rehab Keller PLLC*, which held that emotional distress damages are unavailable for intentional disability discrimination claims under Section 504 and Section 1557).

305. Lagu et al., *supra* note 250, 1389–92; Iezzoni et al., *supra* note 15, at 1373–74; Nicole D. Agaronnik, Elizabeth Pendo, Eric G. Campbell, Julie Ressalam & Lisa I. Iezzoni, *Knowledge of Practicing Physicians About Their Legal Obligations When Caring for Patients with Disability*, 38 HEALTH AFFS. 545, 547–50 (2019); *see also* NAT'L COUNCIL ON DISABILITIES, CURRENT STATE, *supra* note 302, at 14–15.

306. Agaronnik et al., *supra* note 305, 547–50.

307. Iezzoni et al., *supra* note 15, at 1373–74.

308. Lagu et al., *supra* note 250, 1389–92.

beliefs about patients with SUD, and that SUD training and clinical experience with SUD patients were associated with less negative attitudes.[309]

The 2024 Section 1557 final rule requires covered entities to create Section 1557 policies, including clear guidance regarding reasonable modifications to policies and procedures for people with disabilities, and conduct Section 1557 staff training as proactive safeguards against discrimination.[310] The OCR and the DOJ have expanded their efforts to educate health care professionals about their obligations to people with SUD under existing law.[311] In 2018, the OCR launched a public education campaign[312] aimed at clarifying the federal civil rights protections for people with SUD, including access to evidence-based treatment.[313] In 2022, the DOJ issued guidance concerning the ADA's protections for people in treatment or recovery for OUD and other types of SUDs.[314] These enforcement entities should extend their educational initiatives geared at health care providers and systems to new and existing disability antidiscrimination provisions that address the use of clinical algorithms and other patient care decision support tools and their impact on people with disabilities, including individuals with SUD.

C. *Additional Recommendations*

In addition to the recommendations for development and implementation of the Section 1557 final rule, we propose the following statutory and regulatory reforms. Although these recommendations do not serve as the primary focus of this Article, their implementation would increase the impact of our primary proposals.

The CARES Act[315] includes a new nondiscrimination provision that prohibits the discriminatory use of SUD treatment information in health care, employment, worker's compensation, rental or sale of housing, access to courts,

309. Anthony Cazalis, Laura Lambert & Marc Auriacombe, *Stigmatization of People with Addiction by Health Professionals: Current Knowledge. A Scoping Review*, 9 DRUG & ALCOHOL DEPENDENCE REPS. 1, 12 (2023).

310. Nondiscrimination in Health Programs and Activities, 89 Fed. Reg. 37522, 37554–64 (May 6, 2024) (to be codified at 45 C.F.R. pt. 92.8–.9) (Policies and Procedures (§ 92.8) and Training (§ 92.9)).

311. *See* Press Release, U.S. Dep't of Just., Eastern District of Pennsylvania Hosts Roundtable Addressing Medication-Assisted Treatment for Opioid Use Disorder and the Americans with Disabilities Act (Apr. 24, 2019), https://www.justice.gov/usao-edpa/pr/eastern-district-pennsylvania-hosts-roundtable-addressing-medication-assisted-treatment [https://perma.cc/YZ28-PLFV].

312. Oct. 25, 2018 Press Release, *supra* note 155.

313. U.S. DEP'T OF HEALTH & HUM. SERVS. OFF. FOR C.R., ADDICTION AND DISABILITY RIGHTS, *supra* note 157, at 1–2; U.S. DEP'T OF HEALTH & HUM. SERVS. OFF. FOR C.R., NONDISCRIMINATION, *supra* note 158, at 1–2.

314. U.S. DEP'T OF JUST. C.R. DIV., COMBATTING DISCRIMINATION, *supra* note 161, at 1–5.

315. Coronavirus Aid, Relief, and Economic Security Act, Pub. L. No. 116-136, § 3221, 134 Stat. 281, 375–79 (2020) (codified at 42 U.S.C. § 290dd-2).

and social services and benefits funded by federal, state, or local governments.[316] The pertinent CARES Act implementing regulations have not yet been proposed, but it is critical that, when drafted, they interpret the Act's antidiscrimination scope as consistent with existing laws that prohibit disability discrimination by covered entities.[317] In addition, the final Section 1557 rule addressing algorithmic discrimination and other patient care decision support tools should be implemented in a manner congruent with similar regulations for the new antidiscrimination provisions of the CARES Act to support limitations on the use of SUD treatment information, including information tracked by PDMPs and included in patient risk scores, that result in discrimination in health care settings and other areas.[318]

As mentioned previously, the ADA explicitly excludes from its antidiscrimination protections individuals who are currently engaged in the "illegal use of drugs"[319] despite a "safe harbor" exception for individuals who are participating, or have participated, in a rehabilitation program and are no longer engaged in illegal drug use.[320] Needless to say, the ADA's failure to shelter individuals engaged in illegal drug use is counterproductive and health harming, and, as such, should be excised from the statute and other antidiscrimination laws.[321]

It is important to note that, in the context of health care services, the Rehabilitation Act is clear that current illegal drug use is no basis to deny services in hospitals and outpatient facilities or services provided in connection with drug rehabilitation, vocational rehabilitation programs and services, and other covered programs and services to an individual that is otherwise entitled

316. Dineen & Pendo, *Engaging Disability Rights Law*, *supra* note 168, at 43–44. While the regulations implementing the new CARES Act protections have not been proposed at the time of this writing, the authors have argued elsewhere that the scope should be interpreted consistently with existing laws that prohibit disability-based discrimination by covered entities in other settings including health care. Dineen & Pendo, *Substance Use Disorder Discrimination*, *supra* note 177, at 1145.

317. Dineen & Pendo, *Substance Use Disorder Discrimination*, *supra* note 177, at 1145.

318. *Id.*

319. 42 U.S.C. § 12114(a); *see also* 29 U.S.C. § 705(20)(C)(i) (Rehabilitation Act); 42 U.S.C. § 3602(h) (Fair Housing Act). As we and others have argued elsewhere, the exclusion for current illegal use of drugs is harmful and unnecessary, and should be removed from the ADA and other nondiscrimination laws. Dineen & Pendo, *Engaging Disability Rights Law*, *supra* note 168, at 44; Leslie Francis, *Illegal Substance Abuse and Protection from Discrimination in Housing and Employment: Reversing the Exclusion of Illegal Substance Abuse as a Disability*, 2019 UTAH L. REV. 891, 891–92 (2019); Elie G. Aoun & Paul S. Appelbaum, *Ten Years After the ADA Amendment Act (2008): The Relationship Between ADA Employment Discrimination and Substance Use Disorders*, 70 PSYCHIATRIC SERVS. 596, 602–03 (2019).

320. 42 U.S.C. § 12114(b)(1)–(3).

321. Dineen & Pendo, *Engaging Disability Rights Law*, *supra* note 168, at 44; Francis, *supra* note 319, at 891–92; Aoun & Appelbaum, *supra* note 319, at 602–03.

to such services.[322] The ADA's exclusion provision is nonetheless unnecessary, and its removal from the statutory scheme would reflect and reinforce the growing consensus that SUD is a disability worthy of the same protections as other disabilities and antidiscrimination law should be reformed to minimize barriers to access necessary medical treatment, employment, public services, and housing for all individuals with SUD.[323]

In closing, it warrants mention that there have been calls to clarify or restore access to private party disparate impact claims under Section 1557, the laws it amends, or both, to address the harms of algorithmic discrimination.[324] While this Article contends that the use of information generated by PDMP algorithms in clinical settings can be challenged using both disparate treatment and disparate impact theories, the disparate impact framework could be used to challenge a clinical algorithm that does not appear to explicitly target people with disabilities or other protected groups. The authors intend to fully explore the disparate impact framework as applied to PDMP algorithms in future work.

CONCLUSION

The use of algorithmic tools to support clinical decision making, clinical standards of care, and institutional practices and policies related to patient care has witnessed exponential expansion over the last two decades.[325] While such technology holds great promise for improving health care and patient health outcomes, it has already proven to exacerbate inequities that impact marginalized groups, including people with SUD and other disabilities.

For over fifty years, federal antidiscrimination laws have prohibited discrimination against people with disabilities, including in health care. Today, these laws offer a distinct framework and set of tools capable of remedying the growing threat of PDMP algorithmic discrimination and its harms to the health, well-being, and equitable treatment of millions of vulnerable individuals who have SUD, are perceived as having SUD, have been treated for SUD, or have other disabling conditions that are treated with drugs surveilled by PDMPs. Federal disability antidiscrimination laws prohibit health care providers from refusing to prescribe or treat individuals based on their SUD or other disability status, demand individualized, evidence-based assessment of those patients'

322. U.S. DEP'T OF HEALTH & HUM. SERVS. OFF. FOR C.R., ADDICTION AND DISABILITY RIGHTS, *supra* note 158, AT 2; U.S. DEP'T OF HEALTH & HUM. SERVS. OFF. FOR C.R., NONDISCRIMINATION, *supra* note 158, at 1–2. Similarly, there is no statutory exclusion in the new CARES Act protections for individuals whose patient records reveal or appear to reveal current or past SUD. Dineen & Pendo, *Engaging Disability Rights Law*, *supra* note 168, at 44; Dineen & Pendo, *Substance Use Disorder Discrimination*, *supra* note 176, at 1144–45.

323. Dineen & Pendo, *Engaging Disability Rights Law*, *supra* note 168, at 44.

324. *See, e.g.*, Hoffman & Podgurski, *supra* note 202, at 23–26.

325. *See* NAT'L ACAD. OF MED., *supra* note 5, at 1–2.

medical needs, and mandate the implementation of reasonable modifications to policies, practices, and procedures in order to accommodate the needs of individual patients. These laws also expressly proscribe healthcare providers from over relying on the unvalidated and incomplete information generated by PDMP algorithms.

The 2024 ACA Section 1557 final rule presents an opportunity to enhance these protections for people with disabilities, including people who are harmed by the clinical use of PDMP algorithm-generated information and PDMP risk scores. This Article offers recommendations aimed at strengthening the rule as it pertains to all clinical algorithms, harmonizing new and existing antidiscrimination protections, and improving the rule's implementation and enforcement efforts.